

Briefing to the OPTN Board of Directors on **Transparency in Program Selection**

OPTN Ethics Committee

*Prepared by: Laura Schmitt, MS
UNOS Policy and Community Relations Department*

Contents

Executive Summary	1
Background	2
Purpose	4
White Paper for Consideration	4
Overall Sentiment from Public Comment	5
Compliance Analysis	11
Conclusion	12
White Paper	13

Transparency in Program Selection

Sponsoring Committee: Ethics
Public Comment Period: August 3, 2022 – Sept 28, 2022
Board of Directors Meeting: December 5, 2022

Executive Summary

Patient access to transplant continues to be a topic of concern in the transplant community. The Ethics Committee developed this white paper to better understand and address how equity in organ allocation can be improved by considering the beginning of the transplant process: patients who are pursuing evaluation and registration on the waitlist. The Committee applied the ethical principles of organ allocation to the concept of transparency and focused their analysis on how transparency can be improved for patients selecting a transplant program.

The ethical principles of autonomy, equity, procedural justice, and utility are the impetus for more transparent and patient-centered information to enable patients to make better-informed decisions on where they want to pursue transplant evaluation and listing. To address the existing lack of information that is available to patients prior to transplant, the Committee uses five examples to illuminate the ways that increased information is rooted in the ethical principles of organ allocation and can be beneficial to patients selecting a transplant center. The white paper identifies and addresses potential complicating questions that could arise when considering increased transparency, without dictating medical practice or requiring transplant centers to disclose any specific information.

The goal of this white paper is to provide an ethical framework for the OPTN Board of Directors to consider ways in which it can assist the transplant community to improve the transparency of information for patients pursuing transplant evaluation. It also establishes the ethical underpinnings essential for future inclusions of transparency to OPTN policy or data collection. Throughout the white paper, the Committee maintains that patient-centered and program-specific transparency is essential to uphold the OPTN's foundation that "equitable access to the transplant waiting list is the cornerstone of equitable organ allocation."



Background

In May 2021, the OPTN Policy Oversight Committee (POC) identified an opportunity to improve the types of transplant program-specific information and how it is provided to patients at the pre-waitlist stage of transplant. For this white paper, the pre-waitlist phase that is discussed is the period before transplant evaluation when patients know that organ transplant is the next step in their healthcare journey. Most commonly, a community provider, or specialist, refers patients to a transplant program for transplant evaluation. Following the transplant evaluation, the transplant program will review and consider whether the patient is a good fit for transplant at their specific center. If accepted, the patient will be registered to the national waitlist at that transplant program. A less common option is self-referral, where patients are able to refer themselves to a transplant center independent of a community provider or specialist referral.¹

To better understand the issue, the OPTN Ethics Committee (hereafter ‘the Committee’) undertook an ethical analysis considering the ethical principles in support of transparency to inform patient selection of a transplant center. The Final Rule requires the OPTN to develop equitable allocation policies and to promote patient access to transplantation when developing such policies.² The transplant community has expressed overwhelming interest in patient access to organ transplant.³ Such interest is highlighted in the recent report by the National Academies of Sciences, Engineering, and Medicine (NASEM) that identifies areas for improvement in the U.S. transplant system.⁴ Some organizations, such as the Scientific Registry of Transplant Recipients (SRTR), are addressing this interest through patient focus groups aimed at identifying what information is the most pertinent to patients when pursuing transplantation.⁵ Others, including the OPTN, are analyzing and evaluating the impact of Social Determinants of Health and how they can be connected to health disparities, access, and outcomes.^{6,7} The Committee opted to address the lack of transplant program-specific information provided to patients who are pursuing evaluation and registration on the waitlist to improve shared decision-making between the patient and transplant program.

The POC first approved the Committee’s work on this topic in May 2021. At that time, the Committee developed a memo to the OPTN Data Advisory (DAC), Minority Affairs (MAC), and Patients Affairs (PAC) Committees highlighting the ethical principles that support transparent information at the pre-waitlist stage.⁸ The purpose of this memo was to provide a timely ethical analysis that could be used to inform the work of these Committees. To better understand how patient-centered information and access to transplant could be improved, the Committee undertook a formal literature review. The literature noted some areas of interest for patients and highlighted opportunities for improvement that have been identified by both patients and transplant professionals. Currently, transplant centers’ patient acceptance criteria vary drastically, and often times exclusionary criteria are not provided to patients

¹ UNOS Transplant Living, “Getting on the list,” accessed October 20, 2022, <https://transplantliving.org/before-the-transplant/about-organ-allocation/getting-on-the-list/>.

² 42 CFR §121.8(a)(5)

³ Christine Park et al., “A scoping review of inequities in access to organ transplant in the United States, *International Journal for Equity in Health* 21, 22 (Feb 2022). <https://doi.org/10.1186/s12939-021-01616-x>.

⁴ National Research Council, “Realizing the Promise of Equity in the Organ Transplantation System,” 2022, Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

⁵ Scientific Registry of Transplant Recipients, “The Task 5 Initiative,” <https://www.srtr.org/about-srtr/the-task-5-initiative/>.

⁶ Norine W. Chan et al., “Social Determinants of Health Data in Solid Organ Transplantation: National Data Sources and Future Directions,” *American Journal of Transplantation* (May 2022). <https://doi.org/10.1111/ajt.17096>.

⁷ OPTN, “OPTN to study data collection to related social determinants of health,” February 7, 2021, <https://optn.transplant.hrsa.gov/news/optn-to-study-data-collection-to-related-social-determinants-of-health/>.

⁸ OPTN Ethics Committee, *Transparency in Program Selection Memo*, February 2022.

prior to their transplant evaluation.⁹ For many patients, insurance only covers one transplant evaluation, heightening the consequences of center selection.¹⁰ To preserve patient autonomy and support shared decision-making, there is a need to provide additional information to patients at the pre-transplant stage.^{11,12,13} The memo was well received by each group and their feedback was included in the development of the white paper. The DAC, MAC, and PAC were identified as early stakeholders because of their interest and efforts to support work associated with the pre-transplant stage. These groups were also identified to ensure that patient and minority experiences were appropriately captured in the memo and subsequent white papers. Representatives from DAC, MAC, and PAC were invited to join the workgroup and contributed to the completion of the white paper.

This white paper considers the ethical principles of autonomy, procedural justice, equity, and utility:

- “The concept of respect for **autonomy** holds that actions or practices tend to be right insofar as they respect or reflect the exercise of self-determination.”¹⁴
- “**Procedural justice** refers to appraisal of the fairness of how decisions are made.”¹⁵
- **Equity** “refers to fairness in the pattern of distribution of the benefits and burdens of an organ procurement and allocation program.”¹⁶
- “The principle of **utility**, applied to the allocation of organs, thus specifies that allocation should maximize the expected net amount of overall good (that is, good adjusted for accompanying harms), thereby incorporating the principle of beneficence (do good) and the principle of non-maleficence (do no harm).”¹⁷

To further underscore the role the above-mentioned principles play, the Committee considered experiential examples where more transparent information would aid a patient in deciding where to pursue transplant evaluation. These examples include alcohol use, obesity, potentially frail patients, highly sensitized patients, and pediatric living donor liver transplant. These examples are not meant to be inclusive of all patient conditions or information that would be valuable to them, nor do they serve to dictate medical practices to transplant programs. Instead, these examples illuminate how transparent program-specific information could increase shared decision-making and the ethical principles that require such disclosure.

The Committee also explores complicating questions that may arise from an increase in patient-centered transparency during the pre-waitlisting phase. These questions dissect potential concerns and

⁹ Cory R. Schaffhausen et al., “How patients choose kidney transplant centers: A qualitative study of patient experiences,” *Clinical Transplantation* 33, 5 (Mar 2019). <https://doi.org/10.1111/ctr.13523>.

¹⁰ Rachel E. Patzer, et al., “A Population Health Approach to Transplant Access: Challenging the Status Quo,” *American Journal of Kidney Disease* (Feb 2022). <https://doi.org/10.1053/j.ajkd.2022.01.422>.

¹¹ Melania Calestani et al., “Patient attitudes towards kidney transplant listing: Qualitative findings from the ATTOM study,” *Nephrology Dialysis Transplantation* 29, 11 (Nov 2014): 2144-2150. <https://doi.org/10.1093/ndt/gfu188>.

¹² Allison Tong et al., “‘Suspended in a paradox’ – Patient attitudes to wait-listing for kidney transplantation: Systematic review and thematic synthesis of qualitative studies,” *Transplant International* 28, 7 (Jul 2015): 771-787. <https://doi.org/10.1111/tri.12575>.

¹³ Cory R. Schaffhausen et al., “Comparing Pretransplant and Posttransplant Outcomes When Choosing a Transplant Center: Focus Groups and a Randomized Survey,” *Transplantation* 104, 1 (Jan 2020). <https://doi.org/10.1097/TP.0000000000002809>.

¹⁴ OPTN Ethics Committee, *Ethical Principles in the Allocation of Human Organs*, June 2015, accessed March 21, 2022, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-in-the-allocation-of-human-organs/>.

¹⁵ Mark Fondacaro, Bianca Frogner, and Rudolf Moos, “Justice in Health Care Decision-Making: Patients’ Appraisals of Health Care Providers and Health Plan Representatives,” *Social Justice Research* 18, 1 (March 2005): 63-81. <https://doi.org/10.1007/s11211-005-3393-3>.

¹⁶ OPTN Ethics Committee, *Ethical Principles*.

¹⁷ Ibid.

opposition to transparency and emphasize that these concerns can be mitigated and ought not to be a barrier to pursuing increased transparency. These complicating questions provide a balanced perspective by acknowledging and addressing potential challenges from the outset.

The Committee also distinguishes that simply providing information on the internet is insufficient in meeting the needs of all patients by assuming digital access, digital literacy, and accessibility of resources. In order to be patient-centered, the information provided prior to transplant evaluation needs to reach the patient and meet their needs.

Purpose

The white paper may be used to help the OPTN Board develop recommendations that could lead to transplant programs providing more information about clinical criteria for transplant. For example, the white paper could serve as a reference point for transplant programs that want to increase transparency for patients. The white paper highlights the challenge of relying on the internet for patients to access transplant information and illustrates the detriment of assuming digital literacy to achieve health literacy. It also provides an ethical justification for providing certain types of information that patients and their families need access to, and the potential tradeoffs that may need consideration as part of a decision to seek a listing at a particular program. Ultimately, the goal of this paper is to provide the OPTN Board with an ethical framework for developing solutions to improve the decision-making process patients face when selecting a transplant center to pursue evaluation, waitlist registration, and transplantation.

White Paper for Consideration

This white paper analyzes the ethical principles that necessitate the availability of transparent, patient-centered information for patients pursuing transplant evaluation. This analysis uses the ethical principles of autonomy, equity, procedural justice, and utility, which have been cemented as the ethical foundation in organ allocation.¹⁸ In conjunction with the ethical analysis, the Ethics Committee conducted a literature review to better understand the types of information that patients want when selecting a center to pursue transplant listing. In order to provide a robust consideration of transparency, four complicating questions are identified which could be seen as a barrier to transparency. Each question is dissected and ultimately found to be resolvable and should not pose a barrier to transplant.

The Committee outlines five examples of how increased access to transparent, center-specific, and patient-centered information can improve shared decision-making and enhance patient and caregiver autonomy. These examples aim to be representative, not comprehensive, depictions of the types of information patients may want to know and how the information can allow them to make the decision that best aligns with their goals and values. The white paper concludes by highlighting the importance of providing information to patients in a manner that is fully accessible to patients regardless of internet availability, English language comprehension, and physical ability. Patients' health literacy ought not to depend on their digital literacy. This white paper supports transparency and accountability within the transplant system through an ethical analysis to lay the foundation for future improvements in transparency.

¹⁸ Ibid.

Overall Sentiment from Public Comment

The Ethics Committee considers the public comment feedback in light of its efforts to advise the Board of Directors on ethical considerations related to organ transplant and to ensure consideration of all stakeholder perspectives. The white paper received support and appreciation for the Ethics Committee’s efforts to provide ethical guidance and considerations, from a variety of stakeholders during public comment. In addition to feedback submitted by all 11 OPTN regions, **Table 1** represents the 9 OPTN Committees and 12 stakeholder organizations that provided feedback on the white paper.

Table 1: Public Comments from OPTN Committees and Stakeholder Organizations

OPTN Committees	Stakeholder Organizations
Data Advisory	American Nephrology Nurses Association (ANNA)
Histocompatibility	Association of Organ Procurement Organizations (AOPO)
Living Donor	American Society for Histocompatibility and Immunogenetics (ASHI)
Lung Transplantation	American Society of Transplantation (AST)
Minority Affairs	American Society of Transplant Surgeons (ASTS)
Patient Affairs	Cystic Fibrosis Foundation
Pediatric Transplantation	International Society for Heart and Lung Transplantation (ISHLT)
Transplant Administrators	Kidney Donor Conversations
Vascularized Composite Allograft Transplantation	North American Transplant Coordinators Organization (NATCO)
	National Kidney Foundation (NKF)
	Society of Pediatric Liver Transplantation (SPLIT)
	Southeastern Kidney Transplant (SEKTx) Coalition

Overall, this white paper was well supported by a range of stakeholders during public comment. A total of 162 sentiment responses were submitted during regional meetings resulting in a score of 4.0 out of a possible 5.0.¹⁹ While not shown in **Figure 1**, about 84 percent of the sentiment feedback was supportive or strongly supportive, as reflected by the two green bars in the Grand Total. **Figure 1** shows the public comment sentiment feedback by regions at the regional meetings.

Figure 1: Sentiment by Region

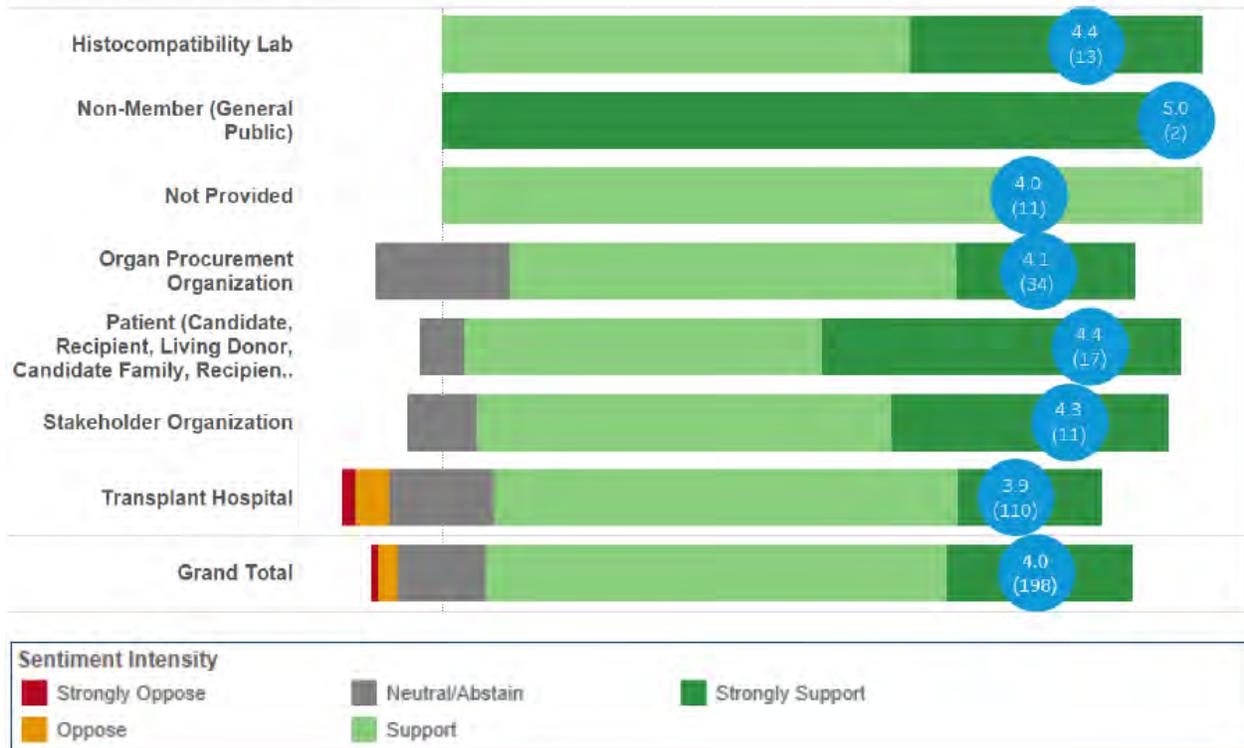


Sentiment by Region

Sentiment opposed or strongly opposed to the white paper was very limited. While opposition to this white paper was exclusively submitted by transplant hospitals, there was still general support for the white paper by this group, as depicted in Figure 2. Figure 2 shows the sentiment by member type, which reflects the sentiment submitted during regional meetings and accompanying public comments.

¹⁹ 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 includes attendees at that 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 the parentheses.

Figure 2: Sentiment by Member Type²⁰



Sentiment by Member Type

Outreach was undertaken to better understand why the transplant hospital opposed or strongly opposed the white paper, however, only one of the transplant hospitals ultimately submitted a public comment. As such, the Ethics Committee considered that the sentiment from the transplant hospitals that did not provide additional details was likely consistent with the transplant centers that expressed concern over operationalizing transparency.

In the feedback received, themes included patient support for transparency, patient access and exacerbating disparities, complicating questions, the inclusion of pediatric-specific information, conceptualizing versus operationalizing transparency, recommendations for next steps, and community alignment. These themes and the Ethics Committee’s responses are discussed in the sections below.

Patient Support for Transparency

While this white paper is developed by the Ethics Committee, the goal was to approach transparency from the patient perspective. It was essential to utilize public comment to gain a better understanding of what patients want and amplify their voices in this process. Patients were very vocal in their support for the white paper and transparency overall. Patients engaged early and often and expressed their support during regional meetings, through sentiment collection, and by submitting public comments.²¹

²⁰ Sentiment by member types reflects the sentiment received during regional meetings and public comment. When submitting a public comment, commenters are additionally asked to identify their member type and degree of sentiment.

²¹ OPTN, Public Comment webpage, Transparency in Program Selection, Amy Mann comment submitted September 9, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>.

The Patient Affairs Committee was very responsive to this white paper and provided extensive feedback on what information and delivery mechanism would be beneficial for patients when selecting a transplant center to pursue evaluation and listing at.²² Notably, patients were candid about sharing their experiences and highlighted how the process plays out in real-time, which is often fleeting for patients:

“From my experience, for a patient not listed, it will take about three months minimum for a listing decision—in a non-emergency situation. For a patient to go through all of the steps in a listing process (scheduling, mental assessment, battery of physical assessments, labs, consolidated assessment, board decision, and listing). If the patient is a candidate for a living donor, add an additional three to six months to the process for a board decision on each candidate-donor and another month or two for scheduling the surgery. If the patient did not select the program that is the right fit for their situation, money, effort, and most importantly, time is wasted. To go to a new program, the process will start over from the beginning again.”²³

In the considerations for the community, the Ethics Committee posed the questions ‘Do community members think that it is important to know what criteria transplant programs use to evaluate patients for listing?’ and ‘What factors are important to you in selecting a program?’ The patient community was active in responding to these questions and provided extensive feedback on what information would be valuable to patients. While this feedback does not change the content of the white paper, it is essential to engage in an open dialogue with patients and families about what information would be helpful to aid in their decision-making. Furthermore, this feedback can serve as a starting point for future work as directed by the OPTN Board of Directors.

Patient Access and Potential Concern for Exacerbating Disparities

Public comment highlighted ongoing concern regarding patient access to transplantation, emphasizing that increases in transparency would not impact the patients who experience barriers to transplant caused by insurance and geography which may subsequently widen the gap in access. Feedback noted that this information is helpful for patients who have a choice, but not all patients have the ability to decide where to pursue transplant either due to dictation by their insurance provider or living in an area that is sparsely populated with transplant programs.^{24, 25}

The Committee considered including this information prior to public comment but opted to focus the white paper on the transplant center selection process alone instead of including the barriers to transplant center selection. This public comment feedback resonated with the Committee and they elected to add a new section to the white paper to address this community concern. The Committee consensus was that patient access fit more appropriately as a complicating question to providing or enacting transparency. The Committee discussed how this section ought to be framed, with specific regard to the title, and did not want to legitimize the concern by endorsing the idea that it would increase disparities. Rather, the Committee felt the feedback was important but wanted it to be considered as a potential component and not highlighted as a known outcome, since further research

²² OPTN, Public Comment webpage, Transparency in Program Selection, OPTN Patient Affairs Committee comment submitted September 28, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

²³ Ibid.

²⁴ OPTN, Public Comment webpage, Transparency in Program Selection, Anonymous comment submitted August 5, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

²⁵ OPTN, Public Comment webpage, Transparency in Program Selection, Calvin Henry comment submitted September 29, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

would be needed to affirm that claim. Ultimately, the Committee added a subsection to Complicating Questions, titled ‘*Access and Transparency*,’ to address this feedback.

Complicating Questions

Another theme in public comment feedback was a concern for unintended consequences and potential misinterpretations of data, which are discussed in the ‘*Complicating Questions*’ section.^{26, 27} Aside from the ‘*Access and Transparency*’ subsection discussed above, the Committee did not feel like the feedback submitted during public comment presented any additional concerns that were not already discussed in this section of the white paper. The Committee felt that the feedback brought up during public comment is adequately acknowledged in the white paper and concluded that these challenges should not inhibit transplant centers from pursuing increases in patient-centered transparency. Ultimately, the Committee discussed and decided against including any additional analysis regarding the existing complicating questions since these comments are sufficiently considered and addressed in the white paper.

Conceptualizing versus Operationalizing Transparency

One major theme in public comment was the request for additional, more specific, and prescriptive direction dictating how transparency will be implemented and monitored. The Committee felt this feedback unearthed a misunderstanding of the purpose of a white paper. One quote characterized it best,

“While the current document reads as a nice summary of ethical principles and the need for transparency, the impact would be increased substantially by specifically addressing how this call for increased transparency will be applied to programs.”²⁸

In discussing and synthesizing the opposition to the white paper, the Committee agreed that fundamentally, the opposition from transplant programs was focused on the technicalities and processes to operationalize transparency more so than what the Committee conceptually presents in the white paper or transparency itself. The Committee recognized the challenge of educating the community on the role and purview of a white paper and suggested ways that this could be more clearly highlighted for future white papers. Ultimately, since it is beyond the scope of the white paper and the Ethics Committee to determine how transparency ought to be applied, implemented, and monitored, this feedback was not used to modify the white paper post-public comment. However, it is important to note here that the community was looking for more direction regarding the next steps of transparency. This distinction is further discussed in the ‘*Recommendations for Next Steps*’ public comment theme below.

²⁶ OPTN, Public Comment webpage, Transparency in Program Selection, UC San Diego Health Care for Transplantation comment submitted September 29, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/?>.

²⁷ OPTN, Public Comment webpage, Transparency in Program Selection, American Society of Transplantation (AST) comment submitted September 27, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/?>.

²⁸ OPTN, Public Comment webpage, *Transparency in Program Selection*, International Society of Heart and Lung Transplantation comment submitted September 27, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/?>.

Inclusion of Pediatric Specific Example

Public comment feedback noted that the white paper lacked recognition of pediatric-specific information, noting the difference in autonomy and equity between adult and pediatric candidates.²⁹ The Committee has previously acknowledged the important needs of pediatric and adolescent patients, especially as they pertain to autonomy, and was generally receptive to including pediatric-specific information.³⁰ A member noted that not every type of patient was represented in the white paper and suggested it may be acceptable to proceed without including pediatric-specific guidance. The Committee ultimately decided that given the public comment feedback and desire to be consistent with previous pediatric statements by the Committee, it would be reasonable to add pediatric-specific information.³¹ When contemplating how best to include pediatric-specific information, the Committee referenced the public comment feedback to include a pediatric living donor liver transplantation example.^{32, 33} Ultimately, the Committee added a subsection to Experiential Examples of Transparency, titled *'Example 5: Pediatric Living Donor Liver Transplantation'* to address this feedback.

Recommendations for Next Steps

In addition to the overall support for the white paper, the community provided suggestions for how the content of the white paper could be developed into policy or data collection. There were recommendations for OPTN Committees to develop guidance documents for transplant centers that are specific to their expertise. For example, the OPTN Lung Transplantation Committee could develop a guidance document outlining what information would be beneficial for transplant centers to provide to patients who are seeking a lung transplant before transplant evaluation.³⁴ Another example is the OPTN Living Donor Committee developing a guidance document on what information transplant centers should provide to both potential living donors and patients seeking a living donor transplant.³⁵ This method would allow the clinical expertise of the specific OPTN Committees to drive recommendations and provide a platform through public comment of continued patient engagement to ensure the guidance reflects the wants and needs of those particular patients.

Additionally, the community viewed this white paper as an initial step for additional OPTN data collection and recommended the use of data-driven information as an alternative to center-identified

²⁹ OPTN, Public Comment webpage, *Transparency in Program Selection*, Sue McDiarmid comment submitted October 3, 2022, accessed October 5, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

³⁰ OPTN Ethics Committee, *Revise General Considerations in Assessment for Transplant Candidacy*, July 2021, accessed April 16, 2022, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/general-considerations-in-assessment-for-transplant-candidacy/>.

³¹ OPTN Ethics Committee, *Ethical Principles of Pediatric Organ Allocation*, November 2014, accessed October 10, 2022, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-of-pediatric-organ-allocation/>.

³² OPTN, Public Comment webpage, *Transparency in Program Selection*, Society of Pediatric Liver Transplantation (SPLIT) comment submitted September 28, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

³³ OPTN, Public Comment webpage, *Transparency in Program Selection*, OPTN Pediatric Transplantation comment submitted September 28, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

³⁴ OPTN, Public Comment webpage, *Transparency in Program Selection*, OPTN Lung Transplantation Committee submitted September 23, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

³⁵ OPTN, Public Comment webpage, *Transparency in Program Selection*, Kidney Donor Conversations submitted August 4, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>?

information to reduce bias or cherry-picking of which data to share and how it should be gathered.^{36,37} While the recommendations shared during public comment are outside of the scope of the Committee and this white paper, it is important to recognize how the community envisions the next steps for transparency.

Community Alignment

Public comment highlighted the alignment between the Transparency in Program Selection white paper and other efforts by the National Academies of Engineering, Sciences, and Medicine (NAEM) and the Scientific Registry of Transplant Recipients (SRTR).^{38, 39} While this feedback did not elicit any changes in the white paper, it is notable that this project is consistent with other widely supported efforts in transplantation by amplifying the patient voice and considering the limitations to accessing transplant. This alignment, and the recognition of it, is important for considering how the ethical justification outlined in the white paper could lead to further projects as directed by the OPTN Board of Directors. It was also important to differentiate the recommendations for next steps that were specific to the OPTN and the alignment across other transplant-wide efforts, beyond the OPTN, to envision the varied and collaborative support.

Compliance Analysis

NOTA and OPTN Final Rule

This white paper is proposed under the authority of the OPTN Final Rule, which tasks the OPTN with developing policies that promote equitable allocation of organs,⁴⁰ and "reduce inequities resulting from socioeconomic status."⁴¹ Furthermore, the Final Rule requires that "[t]ransplant hospitals shall assure that individuals are placed on the waiting list as soon as they are determined to be candidates for transplantation. The OPTN shall advise transplant hospitals of the information needed for such listing."⁴² The Ethics Committee offers the proposed white paper to advise the OPTN Board and committees on the ethical considerations to undertake if they develop policies to address these topics. The Committee theorizes that allocation could be more equitable for all patients, including those of different socioeconomic statuses, if patients are able to make an informed decision about where they are listed, based on the transparency of the listing practices employed by each individual transplant program.

³⁶ OPTN, Public Comment webpage, Transparency in Program Selection, Region 4 submitted September 8, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>.

³⁷ This public comment alluded to the transplant center's ability to manipulate data by selecting what and how information should be shared. For example, instead of a program saying they transplant up to a BMI of 45, their BMI data would reflect that they have never transplanted a patient with a BMI over 40. This supports more data driven information to be shared in lieu of center identified and self-selected information.

³⁸ OPTN, Public Comment webpage, Transparency in Program Selection, Association of Organ Procurement Organizations (AOPO) submitted September 27, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>.

³⁹ OPTN, Public Comment webpage, Transparency in Program Selection, The National Kidney Foundation (NKF) submitted September 28, 2022, accessed September 30, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/transparency-in-program-selection/>.

⁴⁰ 42 CFR §121.4(a)(1)

⁴¹ 42 CFR §121.4(b)

⁴² 42 CFR §121.5(b)

OPTN Strategic Plan

Improve equity in access to transplants: This white paper applies the ethical principles of equity, procedural justice, autonomy, and utility to the concept of transparency, specifically when selecting a transplant center to pursue evaluation and subsequent listing.

Conclusion

The Committee concludes that principles of autonomy, equity, utility, and procedural justice strongly support increased patient access to information about the transplant evaluation process and waitlisting decisions. These principles are fundamental to the organ transplant system and imperative to maintaining an ethical system of allocation.⁴³ Transparent information that contributes to and improves patients' ability to be waitlisted is necessary for ensuring equitable access to care while supporting patient autonomy and utility, while noting that this information needs to be accessible to all patients. Greater transparency about pre-listing information can help patients find programs that are the best fit for their health needs, values, and preferences. This white paper supports transparency and accountability within the transplant system through an ethical analysis that lays the foundation for further review of the OPTN data and policies to enhance patient autonomy. The Committee maintains that patient-centered and program-specific transparency is essential to uphold the OPTN's foundation that "equitable access to the transplant waiting list is the cornerstone of equitable organ allocation."⁴⁴

⁴³ OPTN Ethics Committee, *Ethical Principles*.

⁴⁴ Ibid.

White Paper

1 Introduction

2 Choosing a transplant program¹ (transplant program selection) is a decision with important
3 implications for patients' chances to successfully complete the evaluation process, be waitlisted for
4 an organ, and ultimately receive a transplant. In the United States, research shows that many patients
5 consider multiple programs, and may choose programs far from their home, or pursue listing at
6 multiple programs.^{2,3,4,5,6} Patient acceptance criteria, waiting time, and mortality vary significantly
7 by program, underscoring the importance of transparency about factors which may influence
8 program selection.^{7,8}

9 Disparities in access to transplant remain, including disparities by age, clinical presentation, body mass
10 index (BMI), and race.⁹ Disparities in access to care may be exacerbated by a lack of public information
11 about transplant programs' listing practices. For example, patients may be unaware of differing BMI
12 thresholds, abstinence requirements for substance use, social support requirements, and financial
13 requirements between programs.¹⁰ This can be particularly problematic for patients for whom insurance
14 will only cover one evaluation and who find out during the evaluation process that they will not be listed
15 at a given program because of one of these factors. Even patients who are ultimately listed may benefit
16 from knowing this information earlier. Patients are often unaware of the impact that differences in
17 program-specific acceptance criteria, waiting times, and mortality rates can have on their likelihood of
18 being waitlisted and receiving a transplant.¹¹ Challenges persist in understanding how quickly patients
19 will be placed on the waitlist, and the likelihood that they would be deemed an acceptable candidate for
20 a particular program based on their physical, medical, or social characteristics. Lack of access to data
21 about patient evaluation and listing practices limits the ability to make informed choices about where to
22 seek care.

¹ OPTN Policy 1.2 Definitions defines transplant program as "A component within a transplant hospital that provides transplantation of a particular type of organ."

² Cory R. Schaffhausen et al., "The importance of transplant program measures: Surveys of three national patient advocacy groups," *Clinical Transplantation* 32, 12 (Oct 2018): e13426. <https://doi.org/10.1111/ctr.13426>.

³ Bertram L. Kasiske et al., "The geography of kidney transplantation in the United States," *American Journal of Transplantation* 8, 3 (Feb 2008): 647–657. <https://doi.org/10.1111/j.1600-6143.2007.02130.x>.

⁴ Kendra E. Brett et al., "Perspective on Quality of Care in Kidney Transplantation: A Semistructured Interview Study," *Transplant Direct* 4, 9 (Sep 2018): e383. <https://doi.org/10.1097/TXD.0000000000000820>.

⁵ Mohammad Sanaei Ardekani and Janis M. Orłowski, "Multiple listing in kidney transplantation," *American Journal of Kidney Diseases* 55, 4 (Apr 2010): 717–725. <https://doi.org/10.1053/j.ajkd.2009.11.022>.

⁶ Cory R. Schaffhausen et al., "Comparing Pretransplant and Posttransplant Outcomes When Choosing a Transplant Center: Focus Groups and a Randomized Survey," *Transplantation* 104, 1 (Jan 2020). <https://doi.org/10.1097/TP.0000000000002809>.

⁷ Jesse D. Schold et al., "The pivotal impact of center characteristics on survival of candidates listed for deceased donor kidney transplantation," *Medical Care* 47, 2 (Feb 2009): 146–153. <https://doi.org/10.1097/MLR.0b013e31818475c9>.

⁸ Andrew Wey et al., "Association of pretransplant and posttransplant program ratings with candidate mortality after listing," *American Journal of Transplantation* 19, 2 (Feb 2019): 399–406. <https://doi.org/10.1111/ajt.15032>.

⁹ Christine Park et al., "A scoping review of inequities in access to organ transplant in the United States," *International Journal for Equity in Health* 22 (Feb 2022). <https://doi.org/10.1186/s12939-021-01616-x>.

¹⁰ Cory R. Schaffhausen et al., "Tool to Aid Patients in Selecting a Liver Transplant Center," *Liver Transplantation* 26, 3 (Mar 2020): 337–348. <https://doi.org/10.1002/lt.25715>.

¹¹ Cory R. Schaffhausen et al., "How patients choose kidney transplant centers: A qualitative study of patient experiences," *Clinical Transplantation* 33, 5 (Mar 2019). <https://doi.org/10.1111/ctr.13523>.

23 In light of these challenges and persistent disparities, there is an urgent need to increase patient
 24 access to pre-transplant referral and evaluation information.¹² To this end, this white paper
 25 examines the principles of disclosure in transplantation and considers examples where
 26 transparency of pre-listing information supports equitable and patient-centered access to
 27 transplantation.

28 *Review of Relevant Literature*

29 A systematic literature review was conducted to identify information that patients (transplant
 30 candidates, transplant recipients, transplant support persons, or living donors) believe is relevant to the
 31 selection of a transplant program. During this literature review, information that transplant
 32 professionals thought would be useful for patients was also identified.

33 Table 1-1 provides further details about the literature review screening process and the identified
 34 sources.¹³ Supplemental information on the literature review and article selection process can be found
 35 in Tables 1-2 and 1-3 of Appendix 1.

36 Through the analysis, 17 articles were identified that report data about content desired by patients or
 37 suggested by professionals.^{14,15,16} While most of the articles focus on the kidney transplant population,
 38 a few include patients or transplant professionals of other organ types. However, data was not available
 39 on patients awaiting intestine, lung, or pancreas transplant.^{17,18,19} To summarize the findings, the
 40 desired information fell into six main categories: general information about the transplant program or
 41 staff, referral and evaluation, waitlisting, transplant and perioperative outcomes, long-term follow up
 42 and outcomes, and living donation.^{20,21,22} Table 1-1 provides details about the subtopics of information
 43 desired within each of the six major categories. Patients wanted more information about the
 44 experiences that patients who had similar demographic or disease characteristics as themselves had at a
 45 transplant program, in addition to more general data about volume and outcomes.^{23,24,25} Of note, many
 46 topics that patients wanted to learn more about are areas where data is not currently included in the
 47 Scientific Registry of Transplant Recipients (SRTR) program reports (e.g. patient-reported outcomes

¹² Anil Chandraker et al., "Time for reform in transplant program-specific reporting: AST/ASTS transplantmetrics taskforce," *American Journal of Transplantation* 19, 7 (July 2019): 1888-1895. <https://doi.org/10.1111/ajt.15394>.

¹³ See Appendix 1.

¹⁴ Brett, "Perspective."

¹⁵ Natalia Crenesse-Coizen et al., "Kidney Transplant Evaluation: Inferences from Qualitative Interviews with African American Patients and their Providers," *Journal of Racial and Ethnic Health Disparities* 6, 5 (Oct 2019). <https://doi.org/10.1007/s40615-019-00592-x>.

¹⁶ Elisa J. Gordon et al., "Opportunities for Shared Decision Making in Kidney Transplantation," *American Journal of Transplantation* 13, 5 (May 2013): 1149-1158. <https://doi.org/10.1111/ajt.12195>.

¹⁷ David H. Howard and Bruce Kaplan, "Do report cards include hospital choice? The case of kidney transplantation," *Inquiry* 43, 2 (2006): 150-159. https://doi.org/10.5034/inquiryjrnl_43.2.150.

¹⁸ Syed Ali Husain et al., "Patients prioritize waitlist over posttransplant outcomes when evaluating kidney transplant centers," *American Journal of Transplantation* 18, 11 (Nov 2018): 2781-2790. <https://doi.org/10.1111/ajt.14985>.

¹⁹ Syed Ali Husain et al., "Association Between Declined Offers of Deceased Donor Allograft and Outcomes in Kidney Transplant Candidates," *JAMA Network Open* 2, 8 (Aug 2019). <https://doi.org/10.1001/jamanetworkopen.2019.10312>.

²⁰ Warren T. McKinney et al., "Designing a patient-specific search of transplant program performance and outcomes: Feedback from heart transplant candidates and recipients," *Clinical Transplantation* 35, 2 (Feb 2021). <https://doi.org/10.1111/ctr.14183>.

²¹ Warren T. McKinney et al., "Development of a Patient-specific Search of Transplant Program Outcomes and Characteristics: Feedback from Kidney Transplant Patients," *Transplant Direct* 6, 8 (Aug 2020). <https://doi.org/10.1097/TXD.0000000000001036>

²² Sudeshna Paul et al., "Kidney transplant program waitlisting rate as a metric to assess transplant access," *American Journal of Transplantation* 21, 1 (Jan 2021): 314-321. <https://doi.org/10.1111/ajt.16277>.

²³ Schaffhausen, "How patients."

²⁴ Schaffhausen, "Comparing."

²⁵ Schaffhausen, "Tool."

48 including quality of life and patient satisfaction).²⁶ Furthermore, some professionals assert that not all of
 49 the desired topics are easily assessed or compared (e.g. continuity of providers throughout the
 50 transplant process).^{27,28,29,30} While this literature has provided a better understanding of what
 51 information is important to patients and transplant professionals, it also expounded on the need for
 52 more transparent, consistent, and patient-friendly information to improve shared decision-making.

53 Ethical Principles

54 Autonomy, procedural justice, equity, and utility are critical principles to guide the recommendations as
 55 to what types of information patients should be aware of when making decisions about where and how
 56 to seek transplant care.³¹

57 *Autonomy*

58 The principle of **autonomy** refers to one's ability to be self-directing, have a decisive impact on what
 59 happens to oneself in the future, and, in terms of transplantation, and participate in decisions that lead
 60 to medical treatment, including program selection. The principle of autonomy is also associated with
 61 respect for persons, i.e., the notion that patients should be treated in a way that facilitates choice and
 62 that preserves dignity. Finally, autonomy holds that actions or practices tend to be right insofar as they
 63 support individuals' independent choices, as long as the choices do not impose harm to others.^{32,33} The
 64 accessibility and clear presentation of information relevant to medical decision-making are critical to
 65 support patients' ability to exercise their autonomy. Therefore, autonomy justifies the disclosure of
 66 program-specific information relevant to transplant program selection and shared decision-making.³⁴

67 *Procedural Justice*

68 **Procedural justice** upholds a commitment to treating like cases similarly, transparently, and predictably.
 69 Procedural justice pertains to transparency in program selection in two primary respects: 1) public
 70 accessibility of listing decisions and the rationale for making these decisions, and 2) all justifications of
 71 decisions should rely on rationales that are reasonable and appeal "to evidence, reasons, and principles
 72 that are accepted as relevant by fair-minded people."^{35,36}

²⁶ Scientific Registry of Transplant Recipients, "Program-Specific Reports," accessed June 4, 2022, <https://srrtr.org/reports/program-specific-reports/>.

²⁷ Jesse D. Schold et al., "Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform," *American Journal of Kidney Disease* 74, 3 (Sep 2019): <https://doi.org/10.1053/j.ajkd.2019.02.020>.

²⁸ Sarah E. Van Pilsun Rasmussen et al., "Transplant community perceptions of the benefits and drawbacks of alternative quality metrics for regulation," *Clinical Transplantation* 33, 4 (Apr 2019). <https://doi.org/10.1111/ctr.13500>.

²⁹ Deirdre Sawinski and Jayme E. Locke, "Can you hear me now? Patient preferences for evaluating kidney transplant centers," *American Journal of Transplant* 18, 11 (Nov 2018): 2624. <https://doi.org/10.1111/ajt.15066>.

³⁰ Cory R. Schaffhausen et al., "What patients and members of their support networks ask about transplant program data," *Clinical Transplantation* 31, 12 (Dec 2017). <https://doi.org/10.1111/ctr.13125>.

³¹ 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/>.

³² *Ibid.*

³³ Tom. L Beauchamp and James F. Childress, *Principles of Biomedical Ethics 4th edition* (Oxford: Oxford University Press, 1994).

³⁴ For an example of how shared decision-making can successfully be incorporated into the transplantation process, see: William F. Parker and Marshall H. Chin, "Epistemic Authority and Trust in Shared Decision Making About Organ Transplantation" *AMA Journal of Ethics* 22, 5 (May 2020). <https://doi.org/10.1001/amajethics.2020.408>.

³⁵ Sofia Gruskin and Norman Daniels, "Process Is The Point," *American Journal of Public Health* 98, 9 (Sep 2008): 1573-1577. <https://doi.org/10.2105/AJPH.2007.123182>.

³⁶ Govind Persad, "What Is the Relevance of Procedural Fairness to Making Determinations about Medical Evidence?," *AMA Journal of Ethics* 19, 2 (Feb 2017): 183-191. <https://doi.org/10.1001/journalofethics.2017.19.2.pfor1-1702>.

73 While the exact content of what information procedural justice requires remains somewhat open, in the
 74 context of organ transplantation, it is important for there to be greater symmetry of information
 75 between patients and clinicians about features of transplant program evaluation, waitlisting, and
 76 transplant that could affect a patient’s decision to pursue transplant at a given program. The OPTN
 77 maintains, “procedural justice is critical to preserving public trust and participation in the transplant
 78 system, as it ensures that all patients in need will receive similar treatment.”³⁷

79 Procedural justice also requires that patients have access to the reasons underlying each decision that
 80 affects access to transplant, such as the decision to register a patient for the waitlist (or not), and to
 81 make a patient inactive (or not). Procedural justice does not require every program to provide the same
 82 services or approach, but instead, to provide consistent information on what is available, factors
 83 impacting patient success, and the program’s approach for patient decision-making. Transparency of
 84 information relevant to transplant program selection allows for the transplant listing process to be
 85 evaluated for fairness and consistency, facilitates a patient’s ability to hold a program accountable, and
 86 enhances trust in the system.

87 *Equity*

88 The principle of **equity** refers to removing structural barriers to accessing transplantation and mitigating
 89 undue disadvantage experienced by those who come from structurally marginalized communities or
 90 have fewer resources. The principle of equity invokes a commitment to health equity by focusing on
 91 reducing health disparities commonly defined as the “systematic, plausibly avoidable health differences
 92 adversely affecting social disadvantaged group” such as “race or ethnic group, skin color, religion,
 93 language, or nationality; socioeconomic resources or position; gender, sexual orientation, or gender
 94 identity; age, physical, mental or emotional disability or illness, geography, political or other affiliation;
 95 or other characteristics.”³⁸ Asymmetry of information may worsen outcomes for structurally
 96 marginalized patients, further exacerbating disparities, such as the lack of awareness and differential
 97 use of race as a coefficient in the glomerular filtration rate (GFR) for Black patients with kidney
 98 disease.^{39,40} The lack of accessible information about transplant program listing practices may
 99 disproportionately affect these populations, including those who may be disqualified due to nonmedical
 100 criteria.^{41,42} Transparency of program information facilitates equity in patient access – such as when
 101 insurance policies pay for only one transplant evaluation, a common logistical and financial constraint.⁴³
 102 Even when insurance may cover multiple evaluations, patients and families incur costs and burdens,
 103 including those associated with co-pays, transportation, missed work, and dependent care, among
 104 others. When relevant information is available in a clear and timely manner, it lessens the burden on

³⁷ OPTN Ethics Committee, *Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies*, June 2018, accessed March 1, 2022, https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf.

³⁸ Paula A. Braveman et al., “Health disparities and health equity: The issue is justice,” *American Journal of Public Health* 101, 1 (Dec 2011): S149-S155. <https://doi.org/10.2105/AJPH.2010.300062>.

³⁹ Lesley Inker et al., “New Creatinine and Cystatin C-Based Equations to Estimate GFR without Race,” *New England Journal of Medicine* 385 (Nov 2021). <https://doi.org/10.1056/NEJMoa2102953>.

⁴⁰ During the June 2022 OPTN Board of Directors meeting, the Board approved changes to OPTN policy to disallow the use of race-inclusive eGFR calculators for OPTN purposes.

⁴¹ OPTN Ethics Committee, *Revise General Considerations in Assessment for Transplant Candidacy*, July 2021, accessed April 16, 2022, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/general-considerations-in-assessment-for-transplant-candidacy/>.

⁴² Rachel E. Patzer, et al., “A Population Health Approach to Transplant Access: Challenging the Status Quo,” *American Journal of Kidney Disease* (Feb 2022). <https://doi.org/10.1053/j.ajkd.2022.01.422>.

⁴³ Ibid.

105 patients to self-educate. Self-education is more challenging when patients have fewer resources and
 106 lack access to resources.

107 *Utility*

108 Finally, the principle of **utility**, which in the context of organ allocation refers to the maximization of net
 109 benefit (including promoting graft survival, reducing waste, and improving efficiency), may also justify
 110 greater transparency in listing practice, although this remains an open empirical question.^{44,45} For
 111 example, increasing disclosure of relevant information could lead patients pursuing transplantation to
 112 more rapidly identify a program that fits their needs, thus reducing health care expenditures arising
 113 from multiple waitlist evaluations. Without this, patients may engage in duplicate testing and
 114 evaluations after being predictably turned away from a given program owing to failure to disclose and
 115 explain relevant data. Conversely, transparency of information, clarity of communication, and shared
 116 decision-making are conducive to efficient treatment and increased attention to the patient
 117 perspective.⁴⁶ However, it is possible that transparency in transplant listing criteria may negatively
 118 impact utility, for example, if greater requirements for transparency and disclosure were to negatively
 119 influence transplant programs to be more defensive or conservative. We will address this exception
 120 below. Traditionally, the organ transplant field considers utility related to organ allocation, but utility
 121 also applies to patient optimization of transplant options. Although this white paper demonstrates how
 122 utility may be positively impacted, further research here is needed.

123 **Complicating Questions**

124 Having addressed ethical principles that underlie the need to enhance the accessibility of data to inform
 125 decisions about where to pursue transplant, the below provides four examples of potential negative
 126 consequences that may arise from increased access to information, specifically data, which require
 127 further exploration.

128 *Unintended Consequences of Publishing Data*

129 First, should data be published if doing so might have the unintended consequence of decreasing
 130 programs' willingness to transplant patients whose outcomes they fear may affect other patients or
 131 referring physicians' perceptions of the program? The "cherry-picking" concern here is that an increase
 132 in publicized data might negatively influence transplant programs to engage in defensive patient
 133 selection practices, thus diminishing patients' ability to choose a transplant program. Similar concerns
 134 were previously raised about the implementation of "report cards," a concern which ultimately proved
 135 unfounded, in part due to limited patient use of the data.^{47,48}

⁴⁴ Norman Daniels and James E. Sabin. *Setting Limits Fairly* (Oxford: Oxford University Press, 2002): 45-46.

⁴⁵ *Ethical Principles in the Allocation of Human Organs* defines "the principle of utility, applied to the allocation of organs, thus specifies that allocation should maximize the expected net amount of overall good (that is, good adjusted for accompanying harms), thereby incorporating the principle of beneficence (do good) and the principle of non-maleficence (do no harm)." <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-in-the-allocation-of-human-organs/>.

⁴⁶ L. E. Boulware et al, "Perceived transparency and fairness of the organ allocation system and willingness to donate organs: A national study," *American Journal of Transplant* 7, 7 (July 2007). <https://doi.org/10.1111/j.1600-6143.2007.01848.x>.

⁴⁷ E. C. Schneider and A. M. Epstein, "Use of public performance reports: A survey of patients undergoing cardiac surgery," *Journal of the American Medical Association* 279, 20 (May 1998): 1638-1642. <https://doi.org/10.1001/jama.279.20.1638>.

⁴⁸ Xuan Li et al., "Comparing the Impact of Online Ratings and Report Cards on Patient Choice of Cardiac Surgeon: Large Observational Study," *Journal of Medical Internet Research* 23, 10 (Oct 2021). <https://doi.org/10.2196/28098>.

136 If public reporting contributes adversely to the cherry-picking of patients, prioritizing those most likely
 137 to be predicted to have good outcomes, it may undermine equity and utility.⁴⁹ This underscores the
 138 critical task of determining not only what data are relevant to disclose, but also how these may be
 139 appropriately risk-adjusted and presented predictably and consistently across various transplant
 140 programs. Nonetheless, empirical challenges to appropriately risk adjust should not impede efforts to
 141 promote autonomy and equity.

142 Perhaps much of the concern about the unintended consequences of publishing data can be allayed by
 143 considering the distinction between the terms “data” and “metrics.” Data are quantitative information,
 144 not value judgments. Metrics, by contrast, are “measures that have been developed to support self-
 145 assessment and quality improvement at the provider, hospital and/or health care system level.”⁵⁰ In
 146 light of the distinction between these two terms, it is critical to emphasize that the recommendations
 147 rooted in this principles-based analysis concern the disclosure of data, not the advocacy of which
 148 metrics to utilize. It is also important to acknowledge that making a distinction between “data” and
 149 “metrics” is not to suggest that data are in all cases neutral. The selection of which data to scrutinize and
 150 publicize, and how to frame these strategic decisions, are admittedly values-based decisions, ultimately
 151 affecting the overall interpretation of data. In this case, access to data that could be understood and
 152 used by patients to decide where and how to seek care that aligns with their values is at the core of
 153 autonomy and shared decision-making. To support this, there is a need for transplant programs to
 154 provide information, including data, to patients during the pre-listing stage, the period of
 155 transplantation at which data sharing and transparency is most conspicuously lacking.

156 *Disclosure and Paternalism*

157 Second, what should be done in cases where patients are not necessarily interested in data, but the
 158 referring clinician or transplant professional thinks the data may help the patient in their transplant
 159 program decision? For example, transplant professionals might view the organ acceptance rate ratio as
 160 relevant data even if patients have not yet requested this information.⁵¹ Considerations like this, in turn,
 161 lead to a more fundamental question: is the appropriate data collected to benefit the patient?
 162 Information and data that is disclosed should be done so in a manner that is consistent with promoting
 163 patients’ interests.

164 Regarding potential concerns about paternalism, rather than immediately deciding that particular
 165 information should not be provided, transplant professionals should engage in a discussion with patients
 166 to determine what information would be meaningful to them as well as how to interpret the
 167 information and its potential impact. It may turn out that this is a case in which paternalism stands in
 168 tension with autonomy, where providing patients too much information, or information that is not
 169 relevant or useful, may hinder their decision-making process and impede shared decision-making. Just
 170 as a patient can feel paralyzed in confronting an illness when presented with too many options, so could
 171 the act of over-informing render an already onerous process even more overwhelming.⁵² Thus, it is
 172 important to acknowledge that there are reasonable limits to disclosure and transparency. In keeping

⁴⁹ Jesse D. Schold, Charlotte J. Arrington, and Greg Levine, “Significant alterations in reported clinical practice associated with increased oversight of organ transplant center performance,” *Progress in Transplantation* 20, 3 (Sep 2010): 279-287. <https://doi.org/10.7182/prtr.20.3.bj6mh237p6912251>.

⁵⁰ Robert O. Bonow et al., “ACC/AHA classification of care metrics: performance measures and quality metrics: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures,” *Circulation* 118, 24 (Dec 2008): 2662-2666. <https://doi.org/10.1161/CIRCULATIONAHA.108.191107>.

⁵¹ *Enhance Transplant Program Performance Monitoring System*, OPTN Membership and Professional Standards Committee, August 2021, https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.

⁵² Brett, “Perspectives.”

173 with the principle of autonomy described above, this type of extraneous information should be
 174 determined in advance and should remain unshared in a manner which is consistent and non-
 175 discriminatory (despite that it also may not be completely uniform). This is a question of balance, calling
 176 attention to the importance of engaging patient stakeholders in the process of identifying the
 177 information that they find the most useful to select a program and to increase transparency, which may
 178 also elucidate barriers and facilitators of early access to transplant, or delineate the impact of varied
 179 experiences at the referral and evaluation stages of transplantation.

180 *Potential Misinterpretations in Disclosure*

181 Third, conversely related to the issue of paternalism, are there circumstances where it is ethical to
 182 withhold information when there is evidence (or merely concern) that patients may misinterpret the
 183 data, potentially adding to their anxiety or inducing them to make decisions that do not optimize their
 184 chance to receive a transplant?

185 When disclosing any information, it is always important to consider the possibility that data can be
 186 misinterpreted. If there is a concern that patients are misinterpreting data, the first step should be an
 187 assessment of the reason(s) for the misunderstanding. Does the confusion arise from how the data are
 188 presented? Is the patient receiving conflicting information from other sources? Does the patient lack
 189 comprehension of how the data apply to them? Widespread, persistent misinterpretations of data could
 190 have a negative effect on patients and should lead to a systematic effort to consider how the data are
 191 defined, collected, publicly presented, described, and portrayed.

192 In other words, rather than withholding information because of concerns about how it might be
 193 interpreted, it is better to offer educational resources which aid interpretation. There still may be valid
 194 exceptions to disclosure, but these could be addressed on a case-by-case basis, with specific reasons
 195 proffered when information is withheld. In keeping with a patient-centered approach to transparency, it
 196 is imperative that the public understands both what is shared and, in exceptional cases, the process by
 197 which certain data are determined to remain exclusive.

198 *Access and Transparency*

199 Many patients who seek transplant do not have the option to select their transplant center. This can be
 200 due to geographic considerations, constraints placed by insurance coverage, limitations due to medical
 201 characteristics, or socioeconomic factors. One concern is that patients with these constraints will lack
 202 the ability to take advantage of enhanced informational transparency, while those with greater
 203 resources will be able to “shop around” for programs. This has the potential to increase inequities in the
 204 transplant system.

205 Increased transparency cannot rectify all the systemic inequities and disparities that affect our
 206 healthcare system and society. It is relevant to note that no patient will be made worse off, in an
 207 absolute sense, as a result of enhanced informational transparency. In fact, increased transparency will
 208 likely benefit at least some patients who currently have constrained options. For example, if only a
 209 single transplant evaluation is covered by insurance, access to additional information can help a patient
 210 and referring physician identify the center that is the most likely to meet their needs. In addition, if a
 211 patient’s candidacy is denied, increased transparency will help them identify the best alternative center
 212 from which to seek a second opinion. Increasing transparency should be viewed as a step toward
 213 “levelling-up” all patients.⁵³ This “levelling-up” will achieve the ultimate goal of efficiently matching all

⁵³ Sanjay Kulkarni and Keren Ladin, “Leveling-up versus leveling-down to address health disparities in transplantation,”
American Journal of Transplantation 21, 3 (Mar 2021): 917-918. <https://doi.org/10.1111/ajt.16458>.

214 patients to the program that is best suited for the patient’s needs. Ideally, this efficient matching will
 215 ultimately reduce patients’ wait time and optimize post-transplant outcomes.

216 Experiential Examples of Transparency

217 The ethical principles described above support the disclosure of additional information that may be
 218 helpful to patients when selecting a transplant program. This white paper presents five examples in
 219 which patients might seek greater clarity and transparency during the pre-evaluation phase. Collectively,
 220 these examples demonstrate how information that comprehensively addresses a variety of medical
 221 characteristics can inform transplant evaluations,⁵⁴ thereby impacting imminent decision-making.
 222 Transparency is justified within each example by appealing to **autonomy, procedural justice, equity,**
 223 **and utility** as detailed above.

224 Although this white paper focuses on these representative conditions, which reflect many patients
 225 seeking transplantation, this is not an exhaustive list. A discussion of concrete examples illustrating the
 226 ethical justifications supports ease of understanding for a diverse readership. The patient-facing data
 227 suggested in each example are meant to be illustrative, not exhaustively inclusive. They are not meant
 228 to be comprehensive of all patient experiences, nor do they dictate medical practice to transplant
 229 programs.

230 *Example 1: Alcohol Use*

231 Liver transplant patients may struggle to identify programs available to them before initiating evaluation
 232 and may need information about how selection criteria impact access to transplant, as well as
 233 information specific to their medical characteristics, both of which inform decision-making.⁵⁵ Patients
 234 with end-stage liver disease with a recent history of alcohol use could be concerned about their
 235 perceived fitness for referral.⁵⁶ This subset of patients may ask the question: “If I were to be evaluated
 236 for transplant, how likely is it that I would be waitlisted at that program? What are the requirements, if
 237 any, about abstinence periods?” Information regarding the steps for physician referral and self-referral
 238 promotes autonomy by allowing the patient to search for programs that would accept them for pre-
 239 transplant evaluation despite recent alcohol use while excluding programs that disqualify patients
 240 before evaluation due to recent alcohol use.⁵⁷ If a patient were informed of a required abstinence
 241 period prior to evaluation, they would be able to more adequately consider their options prior to
 242 utilizing their insurance and other out-of-pocket expenses.^{58,59} This underscores the importance of bi-
 243 directional communication prior to the evaluation process, where a patient becomes aware of clear
 244 expectations for what might be required to move a process forward and possibly given resources with
 245 which to do so.

⁵⁴ Schaffhausen, “Comparing.”

⁵⁵ Ibid.

⁵⁶ Philippe Mathurin and Michael R. Lucey, “Liver transplantation in patients with alcoholic-related liver disease: current status and future directions,” *The Lancet Gastroenterology & Hepatology* 5, 5 (May 2020): 507-514. [https://doi.org/10.1016/S2468-1253\(19\)30451-0](https://doi.org/10.1016/S2468-1253(19)30451-0).

⁵⁷ Ibid.

⁵⁸ Sumitha Ganji et al., “Concerns regarding the financial aspects of kidney transplantation: perspectives of pre-transplant patients and their family members,” *Clinical Transplantation* 28, 10 (Oct 2014): 1121-1130. <https://doi.org/10.1111/ctr.12428>.

⁵⁹ Leigh Anne Dageforde et al., “Understanding Patient Barriers to Kidney Transplant Evaluation,” *Transplantation* 99, 7 (July 2015): 1463-1469. <https://doi.org/10.1097/TP.0000000000000543>.

246 *Example 2: Obesity*

247 Obese patients may face challenges in trying to understand a particular program's listing practices for
 248 patients based on high BMI if data are not publicly available, an issue that is exacerbated because obese
 249 patients often face longer time on the waitlist because of their weight.⁶⁰

250 Data show that 21% of kidney transplant programs do not list any patients with BMI greater than 40
 251 kg/m², and 15% do not list patients with BMI greater than 35 kg/m².⁶¹ The median time to transplant for
 252 patients with kidney disease and a BMI greater than or equal to 35 kg/m² is 10 months longer than for
 253 patients with a BMI below 30.⁶² Improved transparency about BMI criteria and time to transplant for
 254 patients with high BMI presents substantial opportunities for improving equity in access. Sharing
 255 information about why BMI matters more at a particular transplant program and why the program sets
 256 a BMI threshold will include obese patients in the process of selecting an appropriate transplant
 257 program, leading to an increase in access for these patients (upholding equity). A patient's likelihood to
 258 have a successful transplant may depend on having some knowledge of the program's record of getting
 259 people transplanted who entered the evaluation with a high BMI.

260 Patients with higher BMIs might benefit from understanding which approaches a program takes to
 261 waitlisting status while they attempt to lose weight to achieve a target BMI. They may also wonder what
 262 resources are available at programs to help them achieve weight loss and meet the program's stated
 263 target. Patients may seek to know which programs offer sleeve gastrectomy in combination with
 264 transplant or robotic-assisted kidney transplant, which show good outcomes for obese patients.⁶³
 265 Providing the program's BMI cut-off would be more patient-friendly and informative than requiring
 266 patients to search through outcome data to inform their decision.

267 To summarize, the principle of autonomy supports publicizing criteria that programs use in deciding
 268 whether to list patients who are obese, how obesity affects time on the waitlist, and what the outcomes
 269 are for obese patients compared to non-obese patients. Autonomy and equity would be served by a
 270 uniform approach to presenting this information accessibly and in a way that does not reduce access for
 271 people because of their weight, but provides information on the rationale for placing limits on BMI.⁶⁴

272 *Example 3: Potentially Frail Patients*

273 Organ transplants are rigorous procedures under the best of circumstances, with lung transplants
 274 reporting 1-and 5-year survival of 85% and 59%, respectively, since 2010.⁶⁵ Patients that have increased
 275 vulnerability to adverse outcomes or decreased capacity to tolerate stressors may be considered higher
 276 risk.⁶⁶ Patients may want to know what additional considerations programs take when deciding who has
 277 the physical capacity to undergo surgery and who is too frail. Frailty is a clinical syndrome, and currently,

⁶⁰ Amy G. Fiedler et al., "Survival in orthotopic heart transplantation in patients with BMI \geq 35 with and without diabetes," *Clinical Transplant* 35, 10 (Oct 2021): e14400. <https://doi.org/10.1111/car.14400>.

⁶¹ Dorry L. Segev et al., "Obesity Impacts Access to Kidney Transplantation," *Journal of the American Society of Nephrology* 19, 2 (Feb 2008): 349-355. <https://doi.org/10.1681/ASN.2007050610>.

⁶² Ivo G. Tzvetanov et al., "Robotic kidney transplantation in the obese patient: 10-year experience from a single center." *American Journal of Transplantation* 20, 2 (Sep 2019): 430-440. <https://doi.org/10.1111/ajt.15626>.

⁶³ Mario Spaggiari et al., "Simultaneous robotic kidney transplantation and bariatric surgery for morbidly obese patients with end-stage renal failure," *American Journal of Transplant* 21, 4 (Apr 2021): 1525-1534. <https://doi.org/10.1111/ajt.16322>.

⁶⁴ Christopher J. Hill et al., "Recipient obesity and outcomes after kidney transplantation: a systematic review and meta-analysis," *Nephrology Dialysis Transplantation* 30, 8 (Aug 2015):1403-1411. <https://doi.org/10.1093/ndt/gfv214>

⁶⁵ Saskia Bos et al., "Survival in adult lung transplantation: where are we in 2020?" *Current Opinion in Organ Transplantation* 25, 3 (June 2020):268-273. <https://doi.org/10.1097/MOT.0000000000000753>.

⁶⁶ Gotaro Kojima, Ann Liljas, and Steve Iliffe, "Frailty syndrome: Implications and challenges for health care policy," *Clinical Journal of the American Society of Nephrology* 11, 4 (Feb 2019):684-693. <https://doi.org/10.2147/RMHP.S168750>.

278 there is no consensus about standards for defining it.^{67,68} Patient awareness of their characteristics that
 279 might lead transplant programs to consider them frail, and knowledge of how a program might evaluate
 280 them for suitability, would allow patients to make wiser choices about evaluation. For example, a
 281 patient with diabetes and below the knee amputation may be limited in their ability to perform a timed
 282 walk test, which is a common test in a transplant evaluation, but may meet other criteria for
 283 robustness.⁶⁹ Patients may also learn whether transplant programs have services to help them increase
 284 endurance.⁷⁰

285 Frail individuals may experience decreased pain tolerance and additional physical trauma from surgical
 286 complications. They may ask: “What resources are available for patients like me at this transplant
 287 program?” Pain management and special attention to this patient population (such as providing access
 288 to pre-habilitation services and anticipating potential complications) will lead to more frail patients
 289 being eligible for transplant, in turn, leading to greater utility.⁷¹

290 Patients who may meet one or more of a programs’ criteria for frailty would have an interest in knowing
 291 if a transplant program offers pre-habilitation services to enhance functional capacity prior to surgery.⁷²
 292 As an alternative to being declined for transplant completely, these patients might benefit from being
 293 made aware of plans for improving their strength and nutrition and what risk factors that might cause a
 294 program to move a patient to inactive status or off the waitlist entirely.

295 Finally, frail patients may have a tougher time rehabilitating or tolerating prescribed post-transplant
 296 drug regimens and therefore derive greater utility from the transparency of information regarding
 297 program standards for management and communication after a surgical procedure. Beyond 1-year and
 298 3-year patient and graft survival, these patients may seek information on other factors that significantly
 299 influence their experienced quality of life, such as oxygen dependence, chronic lung allograft
 300 dysfunction, and the chance of returning home (as opposed to a rehabilitation or skilled nursing facility)
 301 post-transplant.^{73,74}

302 *Example 4: Highly Sensitized*

303 Approximately 35% of patients waitlisted for a kidney transplant are sensitized to human leukocyte
 304 antigens (HLA), which increases their chances of acute rejection after transplant and decreases the
 305 number of individuals who can donate to them.⁷⁵ Highly sensitized patients can expect longer times on
 306 the waitlist and may require multiple evaluations with potential living donors due to cross-match
 307 incompatibility.⁷⁶

⁶⁷ Linda P. Fried et al., “Frailty in older adults: Evidence for a phenotype,” *The Journals of Gerontology, Series A: Biological Sciences and Medical Sciences* 56, 3 (Mar 2001): M146-156. <https://doi.org/10.1093/gerona/56.3.m146>.

⁶⁸ George Bayliss, “Frailty and Kidney Transplantation,” *Rhode Island Medical Journal* 104 (Feb 2021): 15-19.

⁶⁹ Mara A. McAdams-DeMarco et al., “Perceptions and Practices Regarding Frailty in Kidney Transplantation: Results of a National Survey,” *Transplantation* 104, 2 (Feb 2020): 349-356. <https://doi.org/10.1097/TP.0000000000002779>.

⁷⁰ Ram Jagannathan et al., “Physical activity promotion for patients transitioning to dialysis using the “Exercise is Medicine” framework: A multi-center randomized pragmatic trial (EIM-CKD trial) protocol,” *BMC Nephrology* 19, 230 (Sep 2018). <https://doi.org/10.1186/s12882-018-1032-0>.

⁷¹ McAdams-DeMarco, “Perceptions.”

⁷² Fei-Pi Lin et al., “Prehabilitation-Driven Changes in Frailty Metrics Predict Mortality in Patients with Advanced Liver Disease,” *American Journal of Gastroenterology* 11, 10 (Oct 2021): 2105-2117. <https://doi.org/10.14309/ajg.0000000000001376>.

⁷³ Bos, “Survival.”

⁷⁴ Kendra E. Brett et al., “Quality metrics in solid organ transplantation: A systematic review,” *Transplantation* 120, 7 (July 2018): e308-330. <https://doi.org/10.1097/TP.0000000000002149>.

⁷⁵ Enver Akalin, “A New Treatment Option for Highly Sensitized Patients Awaiting Kidney Transplantation,” *American Journal of Kidney Diseases* 71, 4 (Apr 2018): 458-460. <https://doi.org/10.1053/j.ajkd.2017.10.024>.

⁷⁶ Ibid.

308 Highly sensitized patients would arguably benefit from additional data about transplant program
 309 structure that may not be as relevant to less sensitized patients. Transplant programs that incorporate
 310 paired exchange programs or provide intravenous immune globulin (IVIG) therapy may be preferable to
 311 the highly sensitized patient who otherwise may rely solely on the deceased donor allocation system.
 312 Since highly sensitized patients often require more potential living donor evaluations to find a good
 313 match, they may want to know a program’s policy about evaluating multiple potential donors
 314 simultaneously or benefit from additional data about living donation. They may wonder: “does the
 315 program have donor recruitment coaching or assistance in starting a living donor chain?” These patients
 316 may also benefit from understanding the roles of program staff who are dedicated to living donor
 317 services.⁷⁷ Because immunosuppressive and desensitization therapies increase the risk of complications
 318 like infection, highly sensitized patients may have a greater need for access to longer-term program
 319 outcomes beyond the 1-year and 3-year benchmarks.⁷⁸

320 Information about donor selection criteria and outcomes may be relevant for a patient who already has
 321 a potential donor in mind. The autonomy of both the donor and the patient must be respected without
 322 marginalizing the desires of either. The donor, who is a healthy altruistic individual voluntarily
 323 submitting to an extensive battery of tests prior to a substantial surgical procedure, is understandably
 324 warranted in wanting to seek a clear understanding of the workup, para-surgical, and follow up
 325 processes required by the program. Transparency in information regarding these two related, yet
 326 distinct, protocols enhance procedural justice for the donor-recipient pair. Autonomy is also restricted
 327 when patients are relegated to choosing a transplant program based on limited information.

328 *Example 5: Pediatric Living Donor Liver Transplantation*

329 Pediatric patients are especially vulnerable in their inability to exercise absolute autonomy, instead
 330 having to rely on the decision-making of their legal guardian to determine their opportunities for care.⁷⁹
 331 The caregiver’s decision to undergo evaluation at a particular center is exceptionally important given the
 332 limited number of pediatric transplant programs available.⁸⁰ Additionally, many pediatric transplant
 333 centers are low volume performers in comparison to adult transplant centers. As a result, low volume
 334 centers are faced with balancing acceptable risk tolerance with maintaining optimal outcomes, which
 335 could impact their organ acceptance practices.⁸¹ When compounded with the necessity to size match
 336 organs to pediatrics, this can severely limit the potential pool of donor organs and affect a pediatric
 337 candidate’s equitable access to transplant.

338 In an attempt to mitigate some of the equity challenges, a pediatric patient seeking a liver transplant
 339 may benefit from knowing if a particular center performs living donor liver transplants.⁸² This is highly
 340 relevant for pediatric patients, given the need to size-match organs between the donor and

⁷⁷ Jayme E. Locke et al., “Enhanced Advocacy and Health Systems Training Through Patient Navigation Increases Access to Living-donor Kidney Transplantation,” *Transplantation* 104, 1 (Jan 2020). <https://doi.org/10.1097/TP.0000000000002732>.

⁷⁸ Douglas S. Keith and Gayle M. Vranic, “Approach to the Highly Sensitized Kidney Transplant Candidate,” *Clinical Journal of the American Society of Nephrology* 11, 4 (Apr 2016):684-693. <https://doi.org/10.2215/CJN.05930615>.

⁷⁹ OPTN Ethics Committee, *Revise*.

⁸⁰ Abbas Rana, et al., “Pediatric Liver Transplant Center Volume and the Likelihood of Transplantation,” *Pediatrics* 136, 1 (July 2015): e99–e107. <https://doi.org/10.1542/peds.2014-3016>.

⁸¹ Scott A. Elisofon, et al. “Society of pediatric liver transplantation: Current registry status 2011-2018.” *Pediatric transplantation* 24,1 (November 2020): e13605. <https://doi.org/10.1111/petr.13605>.

⁸² OPTN Ethics Committee, “Split Versus Whole Liver Transplantation,” December 2016, accessed October 10, 2022, https://optn.transplant.hrsa.gov/media/1992/ethics_brief_split_liver_201612.pdf.

341 recipient.^{83,84} Caregivers need to be informed that differences in the center and surgical expertise can
 342 expand the donor pool for pediatric candidates.^{85,86} This information will provide caregivers with a
 343 greater ability to make informed decisions for their pediatric candidate. Given the organ longevity
 344 needed and the necessity for long-term outcomes, including quality of life,⁸⁷ transplant center selection
 345 is of the utmost importance to pediatric patients and their caregivers. As the ethical principles outlined
 346 above are not able to be applied in the same manner to pediatric patients, it becomes critically
 347 important for transparent, center-specific information to be provided to this already vulnerable
 348 population in order to protect their interests and needs.^{88, 89}

349 Accessing versus Understanding Information

350 Equitable access to information is essential to ensuring transparency in program selection. However,
 351 merely making information available, and not ensuring that information is usable, understandable, and
 352 accessible to patients will fall short of the goals of protecting patient autonomy and improving equity.
 353 Even if relevant information is available, some patients may have barriers to accessing it or may find the
 354 information challenging to navigate. Patients who can access the information may face difficulties
 355 understanding it or may be overwhelmed by the scope of information.⁹⁰ The process is further
 356 complicated by the fact that pre-transplant concerns will vary depending on whether the person seeking
 357 information is the patient, a potential living donor, or a member of a patient's social support network.⁹¹

358 While optimal health communication poses an important and persistent challenge for public health
 359 agencies and clinicians (and one where guidance is beyond the scope of this paper), this white paper
 360 briefly notes a few issues that must be addressed to achieve the goal of increased transparency in line
 361 with the ethical principles outlined above.

362 *Reliance on Internet for Information Availability*

363 Three overwhelming issues arise when relying on the internet (Worldwide Web) for information:
 364 infrequent internet access, inadequate digital literacy necessary to inform their decisions,⁹² and
 365 insufficient health literacy. The digital information available may not sufficiently inform a patient about
 366 how best to pursue a transplant. The U.S. Department of Education estimates that 16% of American

⁸³ J. B. Otte, et al., "Pediatric liver transplantation: from the full-size liver graft to reduced, split, and living related liver transplantation," *Pediatric surgery international* 13, 5-6 (July 1998): 308-318. <https://doi.org/10.1007/s003830050328>.

⁸⁴ Elisofon, "Society."

⁸⁵ X. Rogiers, et al., "In situ splitting of cadaveric livers. The ultimate expansion of a limited donor pool," *Annals of surgery* 224,3 (Sept 1996): 331-339. <https://doi.org/10.1097/00000658-199609000-00009>.

⁸⁶ Ronald W. Busuttil and John A. Goss, "Split liver transplantation," *Annals of surgery* 229,3 (Mar 1999): 313-21. <https://doi.org/10.1097/00000658-199903000-00003>.

⁸⁷ Nada A. Yazigi, "Long Term Outcomes after Pediatric Liver Transplantation," *Pediatric Gastroenterology, Hepatology & Nutrition* 16, 4 (Dec 2013): 207-218. <https://doi.org/10.5223/pghn.2013.16.4.207>.

⁸⁸ OPTN Ethics Committee, *Revise*.

⁸⁹ OPTN Ethics Committee, "Ethical Principles of Pediatric Organ Allocation," November 2014, accessed October 10, 2022, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-of-pediatric-organ-allocation/>.
⁹⁰ Schaffhausen, "The importance."

⁹¹ Heather F. Hunt et al., "Strategies for Increasing Knowledge, Communication, and Access to Living Donor Transplantation: an Evidence Review to Inform Patient Education," *Current Transplantation Reports* 5, 27 (Feb 2018): 27-44. <https://doi.org/10.1007/s40472-018-0181-1>.

⁹² John B. Horrigan, "Digital Readiness Gaps," *Pew Research Center* (Sep 2016), accessed May 2, 2022, <https://www.pewresearch.org/internet/2016/09/20/digital-readiness-gaps/>.

367 adults are not digitally literate.^{93,94} Digital illiteracy is higher in Black (22%), Hispanic (35%), and
 368 advanced age population (28% in 55-65 years old), which are all groups disproportionately represented
 369 on the waitlist.^{95,96} When a patient is required to rely on technology, which assumes access and digital
 370 literacy to find information on which to make decisions, inadequate internet access and computer ability
 371 impede upon one's autonomy and ability to make well-informed decisions for their health. Health
 372 literacy poses a second concern. Health literacy is defined by the National Institutes of Health (NIH) as
 373 "the degree to which individuals have the ability to find, understand, and use information and services
 374 to inform health-related decisions and actions for themselves and others."⁹⁷ The current system relies
 375 on digital literacy to facilitate health literacy but falls short in meeting the needs of the patient. Low
 376 health literacy has been associated with lower rates of referral to transplant evaluation.⁹⁸ Steps can be
 377 taken to mitigate these inequities to access. For example, a national service that telephonically provides
 378 selection support independent of professional relationships and standard referral patterns⁹⁹ could
 379 enhance autonomy and provide utility to patients regardless of structural barriers and health literacy.

380 *Accessibility of Information:*

381 Equity is furthered by increasing opportunity to access information, not just for people with equipment,
 382 skills, and ability to understand it. Further, resources should be accessible for patients with visual or
 383 hearing impairments, non-native English speakers, and those with limited health or digital literacy.
 384 Information should support autonomy for all, including persons who do not have access to a
 385 smartphone or computer or lack access or functional skills adequate to explore online databases and
 386 materials.

387 Information written for a clinical audience that is not appropriately adapted for patients limits the
 388 proportion of patients that can incorporate the data into their decision-making process. Further, there is
 389 often a disconnect between patient preferences for information and what providers think patients
 390 want.¹⁰⁰ Patient-centered design techniques, including patient co-ownership of the development
 391 process at each stage and iterative refinement with the patient, can avoid user-related design errors
 392 that impede access and dissemination of transplant program information.¹⁰¹

⁹³ U.S. Department of Education, *A Description of U.S. Adults Who Are Not Digitally Literate*, Saida Mamedova and Emily Pawlowski. NCES 2018-161, Washington, D.C.: 2018, <https://nces.ed.gov/pubs2018/2018161.pdf> (accessed March 28, 2022).

⁹⁴ The above report defines "not digitally literate" through the PIAAC requirements for determining basic computer competence: "(1) prior computer use, (2) willingness to take the assessment on the computer, and (3) passing a basic computer test (by successfully completing four of the six simple tasks, such as using a mouse and highlighting text on the screen.)"

⁹⁵ U.S Department of Education, "A Description."

⁹⁶ Park, "A scoping."

⁹⁷ National Institutes of Health, "Health Literacy," accessed May 20, 2022, <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/health-literacy#:~:text=%22Personal%20health%20literacy%20is%20the,actions%20for%20themselves%20and%20others.>

⁹⁸ Vanessa Grubbs et al., "Health Literacy and Access to Kidney Transplantation," *Clinical Journal of the American Society of Nephrology* 4, 9 (Jan 2009): 197-198. <https://doi.org/10.2215/CJN.03290708>.

⁹⁹ Rachel C. Forbes et al., "Implementation of telehealth is associated with improved timeliness to kidney transplant waitlist evaluation," *Journal of Telemedicine and Telecare* 24, 7 (Aug 2018): 485-491. <https://doi.org/10.1177/1357633X17715526>.

¹⁰⁰ Christine Bechtel and Debra L. Ness, "If You Build It, Will They Come? Designing Truly Patient-Centered Health Care," *Health Affairs* 25, 9 (May 2010). <https://doi.org/10.1377/hlthaff.2010.0305>.

¹⁰¹ Victor P. Cornet et al., "Patient-centered Design Grounded in User and Clinical Realities: Towards Valid Digital Health," *Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care* 8, 1 (Sep 2019): 100-104. <https://doi.org/10.1177/2327857919081023>.

393 Conclusion

394 This white paper concludes that principles of autonomy, equity, utility, and procedural justice strongly
395 support increasing patient access to pre-waitlist data and information about the transplant evaluation
396 process and waitlisting decisions. These principles are core to the organ transplant system and
397 imperative to maintain an ethical system of allocation.¹⁰² Transparent data that contribute to patients'
398 ability to be waitlisted is necessary for ensuring equitable access to care while supporting patient
399 autonomy and utility. Greater transparency about pre-listing information can help patients find
400 programs that are the best fit for their health needs, values, and preferences. This white paper supports
401 transparency and accountability within the transplant system through an ethical analysis that lays the
402 foundation for future improvements.

#

¹⁰² OPTN Ethics Committee, *Ethical Principles*.

403 **Table 1-1: Types of information desired by patients and professionals, by phase of transplant process)**

Types of Information desired by phase of transplant process	Who the information is desired by and what literature it was found in
General center data	
Center years performing transplant	Patients (Husain 2018)
Clinical practice differences from other centers	Professionals (Gordon 2013)
Continuity of providers throughout transplant process	Patients (Husain 2018)
Distance from home	Patients (Husain 2018)
Outreach or support program	Patients (Husain 2018, Schaffhausen 2019)
Participation in research or innovation	Patients (Schaffhausen, 2019)
Patient satisfaction	Professionals (Brett 2018, Husain 2018, van Pilsum Rasmussen 2019)
Reputation	Patients (Husain 2018)
Risk tolerance of the center	Professionals (Gordon 2013)
Staff & surgeon training	Patients (Husain 2018, Schaffhausen 2019)
Teaching institution	Patients (Husain 2018, Schaffhausen 2019)
Referral	
Citizenship status of candidate donor or recipient	Patients (Schaffhausen 2017)
Cost of pre-transplant evaluation	Patients (Husain 2018)
Insurance accepted	Patients (Husain 2018)
Multiple/alternative center listing for transplant	Patients (Schaffhausen 2017, Crenesse-Covien 2019, Schaffhausen 2019, Schaffhausen 2020)
Patient qualifications for transplant	Patients (Schaffhausen 2017, Schaffhausen 2019)
Quality of life among referred patients	Professionals (van Pilsum Rasmussen 2019)
Second opinion evaluations	Patients (Schaffhausen 2017)
Waitlisting rate (ratio of patients who are waitlisted relative to the person-years referred for evaluation) / ease of getting waitlisted	Patients (Schaffhausen 2017, Husain 2018) Professionals (Paul 2021)
Waitlisting	
Health status changes for waitlisted patients	Professionals (Brett 2018)
Organ acceptance & refusal trends	Professionals (Husain 2017, 2019, Schold 2019, van Pilsum Rasmussen 2019)
Organ acceptance, high-risk organs	Patients (Schaffhausen 2017, Schaffhausen 2019)
Quality of life among waitlisted patients	Professionals (van Pilsum Rasmussen 2019)

Types of Information desired by phase of transplant process	Who the information is desired by and what literature it was found in
Time on waiting list / time to transplant	Patients (Schaffhausen 2017, Husain 2018, Schaffhausen 2019) Professionals (Gordon 2013, van Pilsum Rasmussen 2019)
Transplant rate	Professionals (Sawinski 2018, Schold 2019, Schaffhausen 2020) Patients (Husain 2018)
Variations in illness severity at time of transplant	Patients (Schaffhausen 2017, Schaffhausen 2020)
Variations in organ availability	Professionals (Husain 2018)
Waitlist mortality	Patients (Schaffhausen 2019) Professionals (Brett 2018, Schold 2019, van Pilsum Rasmussen 2019)
Transplant	
Cost of procedure	Patients (Schaffhausen 2017, Husain 2018)
Volume of transplants, overall	Professionals (Gordon 2013, van Pilsum Rasmussen 2019) Patients (Schaffhausen 2017, Husain 2018)
Volume of transplants, based on donor-specific health characteristics (e.g. increased risk, HCV)	Professionals (McKinney 2020) Patients (Schaffhausen 2020)
Volume of transplants, based on patient-specific health characteristics (e.g. age, BMI)	Patients (Husain 2018, McKinney 2020, Schaffhausen 2017, Schaffhausen 2020)
Volume of transplants, complex cases	Patients (Husain 2018)
Post-transplant	
Complications & readmissions	Patients (Husain 2018) Professionals (Brett 2018, van Pilsum Rasmussen 2019)
Functional status of recipients	Professionals (van Pilsum Rasmussen 2019)
Immunosuppression regimen variations	Professionals (Gordon 2013)
Infectious disease transmission	Professionals (Brett 2018)
Patient-reported outcomes	Professionals (Schold 2019)
Patient or graft survival	Patients (Husain 2018, Schaffhausen 2017, Schaffhausen 2019, Schaffhausen 2020) Professionals (Gordon 2013, Howard 2006, Schold 2019)
Post-transplant care expectations and ease	Patients (Husain 2018) Professionals (Gordon 2013)
Post-transplant length of stay	Professionals (Brett 2018, van Pilsum Rasmussen 2019)

Types of Information desired by phase of transplant process	Who the information is desired by and what literature it was found in
Quality of life among transplanted patients	Professionals (van Pilsun Rasmussen 2019)
Living donor	
Living donor outcomes	Patients (Schaffhausen 2017)

404
405
406

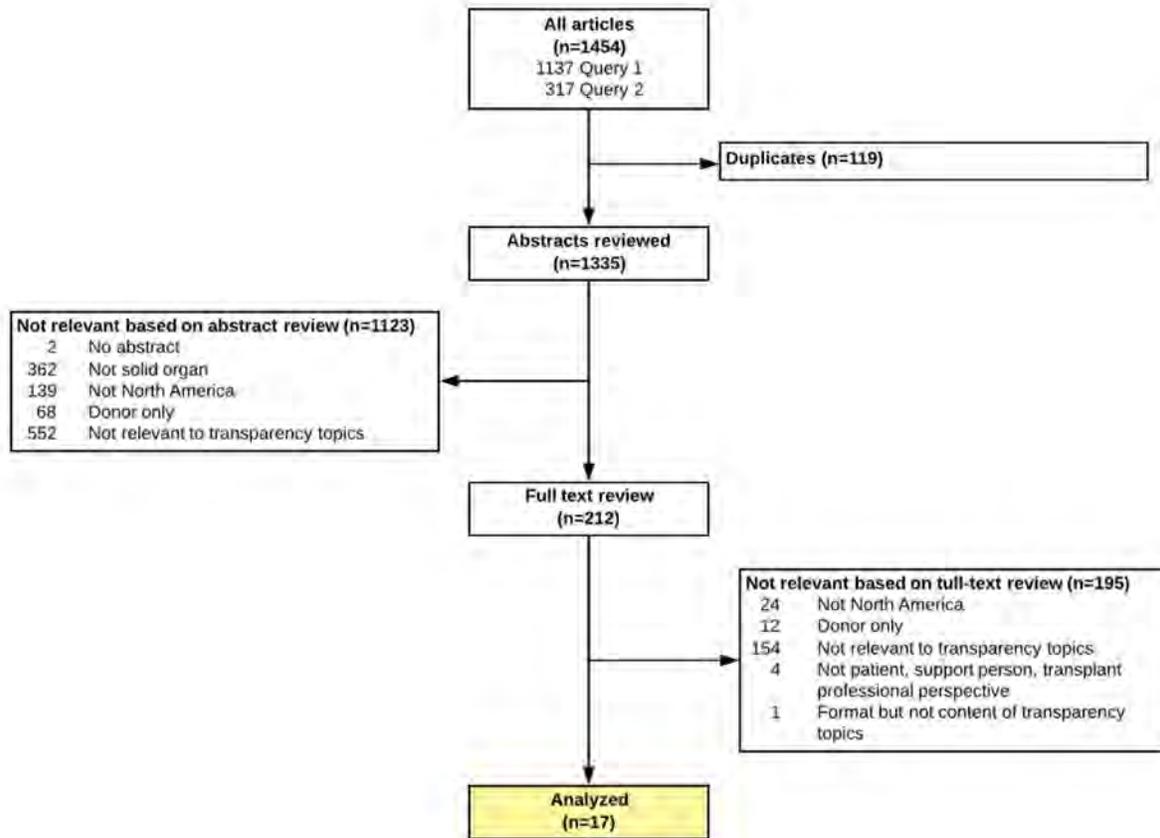
Table 1-2: Database search terms

	Question 1: Patient selection of transplant programs	Question 2: Patient selection of transplant programs in Hispanic and African American patients
Medline (EBSCO)	<p>356 Results English Language ((TI transplant* OR AB transplant*) N5 (TI center* OR AB center* OR TI program OR AB program OR TI programs OR AB programs)) AND (MM "Patient Preference" OR MM "Patient Education as Topic" OR MM "Choice Behavior" OR (TI patient-centered OR TI patient-specific OR AB patient-centered OR AB patient-specific OR ((TI patient* OR AB patient* OR TI candidate* OR AB candidate* OR TI recipient* OR AB recipient) AND (MH "Decision Making")) OR ((TI patient* OR AB patient* OR TI candidate* OR AB candidate* OR TI recipient* OR AB recipient*) N7 (TI decision-making OR AB decision-making OR TI decision-support OR AB decision-support OR TI preference* OR AB preference* OR TI perception* OR AB perception*)))) AND (LA English) NOT (TI clinical-decision-making OR AB clinical-decision-making)</p>	<p>178 Results English Language (MH "Organ Transplantation+" OR MH "Transplant Recipients" OR ((TI transplant* OR AB transplant*) N5 (TI organ OR AB organ OR TI organs OR AB organs OR TI liver* OR AB liver* OR TI kidney* OR AB kidney* OR TI heart* OR AB heart* OR TI lung* OR AB lung* OR TI pancreas OR AB pancreas OR TI center* OR AB center* OR TI program OR AB program OR TI programs OR AB programs OR recipient*))) AND (MM "Patient Preference" OR MM "Patient Education as Topic" OR MM "Choice Behavior" OR (TI patient-centered OR TI patient-specific OR AB patient-centered OR AB patient-specific OR ((TI patient* OR AB patient* OR TI candidate* OR AB candidate* OR TI recipient* OR AB recipient*) AND (MH "Decision Making")) OR ((TI patient* OR AB patient* OR TI candidate* OR AB candidate* OR TI recipient* OR AB recipient*) N7 (TI decision-making OR AB decision-making OR TI decision-support OR AB decision-support OR TI preference* OR AB preference* OR TI perception* OR AB perception*)))) AND (MH "Ethnic Groups+" OR MH "Minority Groups+" OR MH "Minority Health+" OR TI african-american* OR AB african-american* OR TI afro-american* OR AB afro-american* OR TI black* OR AB black* OR TI Hispanic* OR AB Hispanic* OR TI Mexican* OR AB Mexican* OR TI latino* OR AB latino* OR TI Latina* OR AB latina* OR TI latinx OR AB latinx OR TI minorit* OR AB minorit* OR TI race OR AB race OR TI racial OR AB racial OR TI ethnic-group* OR AB ethnic-group* OR TI ethnicit* OR AB ethnicit*) AND (LA English)</p>

	Question 1: Patient selection of transplant programs	Question 2: Patient selection of transplant programs in Hispanic and African American patients
PubMed narrow	<p>Exact phrases for transplant centers/programs 368 Results English Language ((transplant-center*[tiab] OR transplant-program[tiab] OR transplant-programs[tiab] OR transplantation-center*[tiab] OR transplantation-program[tiab] OR transplantation-programs[tiab]) AND ("Patient Preference"[majr] OR "Choice Behavior"[majr:noexp] OR "Patient Education as Topic"[majr] OR patient-centered[tiab] OR patient-specific[tiab] OR ((patient*[tiab] OR candidate*[tiab] OR recipient*[tiab]) AND ("Decision-Making"[mesh:noexp] OR decision-making[tiab] OR decision-support[tiab] OR preference*[tiab] OR perception*[tiab]))) AND english[filter]) NOT (clinical-decision-making[tiab])</p>	<p>Exact phrases for transplant centers/programs/organs 277 Results English Language ("Organ Transplantation"[mesh] OR "Transplant Recipients"[mesh] OR organ-transplant*[tiab] OR liver-transplant*[tiab] OR heart-transplant*[tiab] OR kidney-transplant*[tiab] OR lung-transplant*[tiab] OR pancreas-transplant*[tiab] OR transplant-center*[tiab] OR transplant-program[tiab] OR transplant-programs[tiab] OR transplantation-center*[tiab] OR transplantation-program[tiab] OR transplantation-programs[tiab] OR transplant-recipient*[tiab]) AND ("Patient Preference"[majr] OR "Choice Behavior"[majr:noexp] OR "Patient Education as Topic"[majr] OR patient-centered[tiab] OR patient-specific[tiab] OR ((patient*[tiab] OR candidate*[tiab] OR recipient*[tiab]) AND ("Decision-Making"[mesh:noexp] OR decision-making[tiab] OR decision-support[tiab] OR preference*[tiab] OR perception*[tiab]))) AND ("Ethnic Groups"[mesh] OR "Minority Groups"[mesh] OR "Minority Health"[mesh] OR african-american*[tiab] OR afro-american*[tiab] OR black*[tiab] OR Hispanic*[tiab] OR Mexican*[tiab] OR latino*[tiab] OR Latina*[tiab] OR latinx[tiab] OR minorit*[tiab] OR race[tiab] OR racial[tiab] OR ethnic-group*[tiab] OR ethnicit*[tiab]) AND english[filter])</p>
PubMed broad <i>These search terms were used.</i>	<p>Transplant with center or program in title/abstract 1132 Results English Language, remove clinical decision-making from title/abstract ((transplant*[tiab]) AND (center[tiab] OR centers[tiab] OR program[tiab] OR programs[tiab]) AND ("Patient Preference"[majr] OR "Choice Behavior"[majr:noexp] OR "Patient Education as Topic"[majr] OR patient-centered[tiab] OR patient-specific[tiab] OR ((patient*[tiab] OR candidate*[tiab] OR recipient*[tiab]) AND ("Decision-Making"[mesh:noexp] OR decision-making[tiab] OR decision-support[tiab] OR preference*[tiab] OR perception*[tiab]))) AND english[filter]) NOT (clinical-decision-making[tiab])</p>	<p>Transplant within title/abstract of organs/programs/centers 314 Results English Language ("Organ Transplantation"[mesh] OR "Transplant Recipients"[mesh] OR ((transplant*[tiab]) AND (organ[tiab] OR kidney*[tiab] OR liver[tiab] OR heart[tiab] OR lung*[tiab] OR pancreas[tiab] OR center*[tiab] OR program[tiab] OR programs[tiab] OR recipient*[tiab]))) AND ("Patient Preference"[majr] OR "Choice Behavior"[majr:noexp] OR "Patient Education as Topic"[majr] OR patient-centered[tiab] OR patient-specific[tiab] OR ((patient*[tiab] OR candidate*[tiab] OR recipient*[tiab]) AND ("Decision-Making"[mesh:noexp] OR decision-making[tiab] OR decision-support[tiab] OR preference*[tiab] OR perception*[tiab]))) AND ("Ethnic Groups"[mesh] OR "Minority Groups"[mesh] OR "Minority Health"[mesh] OR african-american*[tiab] OR afro-american*[tiab] OR black*[tiab] OR Hispanic*[tiab] OR Mexican*[tiab] OR latino*[tiab] OR Latina*[tiab] OR latinx[tiab] OR minorit*[tiab] OR race[tiab] OR racial[tiab] OR ethnic-group*[tiab] OR ethnicit*[tiab]) AND english[filter])</p>

408

Table 1-3: Article selection flowsheet



409

#