Public Comment Proposals

Winter 2021

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK OPTN

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OPTN

Request for Feedback

Develop Measures for Heart Primary Graft Dysfunction

OPTN Heart Transplantation Committee

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OPTN

Develop Measures for Heart Primary Graft Dysfunction

Affected Policies: *N/A*
Sponsoring Committee: *Heart Transplantation*
Public Comment Period: *January 21, 2021 – March 23, 2021*

Executive Summary

Primary Graft Dysfunction (PGD) is the leading cause of 30-day mortality post-heart transplantation.[1] However, the Organ Procurement and Transplantation Network (OPTN) does not collect post-transplant information that could identify recipients who develop primary graft dysfunction. The OPTN Heart Transplantation Committee (hereinafter "the Committee") is requesting input from the community to solicit suggestions and feedback regarding potential data elements to identify PGD in heart transplant recipients and its impact on outcomes.[2]

This document contains a list of additional data elements the Committee believes are essential to identify PGD. The transplant community is asked to review and assess the comprehensiveness of the data elements, as well as the proposed collection timeframes.

This document is not a proposal, but instead a request for feedback and suggestions concerning new data elements that should be considered. The input received will be used to develop a future data collection proposal that would support the OPTN strategic goal of improving waitlisted patient, living donor, and transplant recipient outcomes. The information that will eventually be collected should allow the Committee to monitor outcomes for recipients with PGD and to aid in future policy development. This project can provide information to assist in developing a continuous distribution heart allocation framework and potential data collection requests in the future.

[1] Singh, Sanjeet, Singh Avtaar, Dalzell, Jonathan R, Berry, Colin, and Al-Attar, Nawwar. "Primary Graft Dysfunction after Heart Transplantation: A Thorn amongst the Roses." *Heart Failure Reviews* 24, no. 5 (2019): 805-20.
[2] On July 1, 2020, the OPTN Thoracic Organ Transplantation Committee was disbanded and replaced by an OPTN Heart Transplantation Committee and an OPTN Lung Transplantation Committee.

Background

PGD is a leading cause of early mortality post-heart transplantation[3] with an incidence that varies from 2.3 percent to 28.2 percent.[4] PGD presents as ventricular dysfunction occurring within 24 hours post-transplant.[5] Additionally, there is no identifiable secondary cause such as hyperacute rejection, pulmonary hypertension, or known surgical complications.[6] A 2013 the International Society of Heart and Lung Transplantation (ISHLT) consensus conference described a classification system to enable a more uniform diagnosis of PGD and improve comparisons between centers in regard to its incidence and treatment options.[7] The classification system included a severity scale.[8] **Appendix A** contains the consensus statements and severity scale.

Following the conference, the community has sought to further clarify PGD's reach and impact on recipient mortality. For instance, a study applying the new ISHLT consensus classification showed that severe PGD (i.e. need for mechanical circulatory support following transplantation) is associated with poor outcomes.[9] This two-center study described a 518 patient cohort with a 14 percent prevalence of PGD and a mortality of 54 percent in patients with severe PGD.[10] In addition, another study evaluating the outcomes of a different cohort of 195 patients found worse 30-day and one-year mortality in patients transplanted who developed moderate and severe PGD as defined by ISHLT criteria compared to those diagnosed with mild PGD or no PGD.[11] The patients also experienced increased ICU length of stay, more postoperative bleeding, and increased infections. A consortium of Virginia cardiac transplant programs also examined outcomes and resource utilization following the development of PGF using the ISHLT definition.[12] Of the 718 patients studied, 15.3 percent developed PGD and these patients had longer ICU length of stay, longer duration of intubation, more multi-organ failure, and higher mortality.

Two recent studies from Canada and the United Kingdom also applied the use of the ISHLT PGD criteria to outcomes. In 2019, a study of a 412 patient cohort at the University of Toronto reported significantly elevated hazard ratios of 7.0 and 15.9 one-year mortality for patients with moderate and severe PGD,

[3] Singh, Sanjeet, et al. "Primary Graft Dysfunction." 805-20.
[4] Kobashigawa, Jon, Zuckermann, Andreas, Macdonald, Peter, Leprince, Pascal, Esmailian, Fardad, Luu, Minh, Mancini, Donna, Patel, Jignesh, Razi, Rabia, Reichenspurner, Hermann, Russell, Stuart, Segovia, Javier, Smedira, Nicolas, Stehlik, Josef, and Wagner, Florian. "Report from a Consensus Conference on Primary Graft Dysfunction after Cardiac Transplantation." *The Journal of Heart and Lung Transplantation* 33, no. 4 (2014): 327-40.
[5] Kobashigawa, Jon, et al. "Report." 337.
[6] Kobashigawa, Jon, et al. "Report." 337.
[7] Kobashigawa, Jon, et al. "Report." 327-40.
[8] Kobashigawa, Jon, et al. "Report." 327-40.
[9] Sabatino, Mario, Vitale, Giuseppe, Manfredini, Valentina, Masetti, Marco, Borgese, Laura, Maria Raffa, Giuseppe, Loforte, Antonio, Martin Suarez, Sofia, Falletta, Calogero, Marinelli, Giuseppe, Clemenza, Francesco, Grigioni, Francesco, and Potena, Luciano. "Clinical Relevance of the International Society for Heart and Lung Transplantation Consensus Classification of Primary Graft Dysfunction after Heart Transplantation: Epidemiology, Risk Factors, and Outcomes." *The Journal of Heart and Lung Transplantation* 36, no. 11 (2017): 1217-225.
[10] Sabatino, Mario, et al. "Clinical Relevance." 1217-225.
[11] Squiers, John J, Saracino, Giovanna, Chamogeorgakis, Themistokles, MacHannaford, Juan C, Rafael, Aldo E, Gonzalez-Stawinski, Gonzalo V, Hall, Shelley A, DiMaio, J Michael, and Lima, Brian. "Application of the International Society for Heart and Lung Transplantation (ISHLT) Criteria for Primary Graft Dysfunction after Cardiac Transplantation: Outcomes from a High-volume Centre." European Journal of Cardio-thoracic Surgery 51, no. 2 (2017): 263-70.
[12] Quader, Mohammed, Hawkins, Robert B, Mehaffey, J. Hunter, Mazimba, Sula, Ailawadi, Gorav, Yarboro, Leora, Rich, Jeffrey, Speir, Alan, Fonner, Clifford, Wolfe, Luke, and Kasirajan, Vigneshwar. "Primary Graft Dysfunction after Heart Transplantation: Outcomes and Resource Utilization." *Journal of Cardiac Surgery* 34, no. 12 (2019): 1519-525.

respectively.[13] Similarly, a 2019 study examined the incidence, risk factors and outcomes following PGD in all adult heart transplant patients in the United Kingdom from October 2012 to October 2015 using the ISHLT consensus definition[14]. For the 450 adults included in this study, the incidence of PGD was 36.2 percent with an increased one-month mortality with the highest mortality in the severe PGD group.

Many donor, recipient, and procedural risk factors have been found to be associated with the development of PGD.[15] These include donor age, recipient age, recipient inotropic support, and pre-transplant mechanical support.[16] Ischemia time is also considered an independent risk factor.[17] Nonetheless, it is difficult to definitively establish the risk factors, according to researchers, because of the variability in the studies that have been performed. When the OPTN Thoracic Committee considered a PGD project in 2014, there were concerns that there might be a rising incidence of PGD at that time. However, research studies suggest that it is difficult to determine whether there has been an increase or decrease.[18,19] Furthermore, it is difficult to know whether future allocation changes, such as the continuous distribution of hearts, may impact the rate of PGD. An understanding of the gravity of the problem is needed.

Presently, transplant programs are reviewed and compared primarily by 30-day, one- and three-year mortality rates. However, PGD adds considerable morbidity in addition to mortality to transplant recipients' outcomes, especially within the first year following transplant. It is important for a patient to be aware of what the chances are that mechanical support post-transplant will be required, which usually means longer ICU stays, more complications, slower recovery, long hospitalizations, more need for rehabilitation, or additional prolonged care. Because the OPTN does not collect post-transplant data specific to PGD, it is not possible to make program-level comparisons. This project is a first step at addressing this knowledge gap.

Currently, analysis of PGD is limited due to the lack of available data. The Committee had twice before started projects addressing PGD. In 2014, the Committee was contacted by the Membership and Professional Standards Committee (MPSC) with information suggesting that the incidence of PGD may have greater occurrences than acknowledged because the OPTN did not collect sufficient data for tracking it.[20] However, the Committee chose to put this effort on hold while the members focused on comprehensively modifying adult heart allocation policy. The Committee again considered a PGD project in 2018. However, the Committee's PGD efforts were put on hold because as they began to analyze the recent adoption of the new adult heart allocation policy, as well as other heart projects.

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[13] Foroutan, Farid, and Ross, Heather J. "Primary Graft Dysfunction: The Devil Is in the Details." *Transplantation* 103, no. 2 (2019): 229-30.

[14] Avtaar Singh, Sanjeet Singh, Banner, Nicholas R, Rushton, Sally, Simon, Andre R, Berry, Colin, and Al-Attar, Nawwar. "ISHLT Primary Graft Dysfunction Incidence, Risk Factors, and Outcome: A UK National Study." *Transplantation* 103, no. 2 (2019): 336-43.

[15] Nicoara, Alina, Ruffin, David, Cooter, Mary, Patel, Chetan B, Thompson, Annemarie, Schroder, Jacob N, Daneshmand, Mani A, Hernandez, Adrian F, Rogers, Joseph G, Podgoreanu, Mihai V, Swaminathan, Madhav, Kretzer, Adam, Stafford-Smith, Mark, Milano, Carmelo A, and Bartz, Raquel R. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." *American Journal of Transplantation* 18, no. 6 (2018): 1466.

[16] Nicoara, Alina, et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." 1466.

[17] Nicoara, Alina, et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." 1466.

[18] Kobashigawa, Jon, et al. "Report." 328.

[19] Quader, Mohammed, et al. "Primary Graft Dysfunction after Heart Transplantation." 1520.

[20] OPTN, Thoracic Organ Transplantation Committee, Meeting summary, September 18, 2014.

Development Process

In August 2020, the Committee identified PGD as a high priority project and sought to identify the most important parameters needed to identify PGD. They acknowledged that current data collection efforts were inadequate to actually define PGD based on the recent consensus definition. Data collection that accurately captures the incidence of PGD will enable the heart transplant community to better assess the impact PGD has on the morbidity and mortality of heart transplant recipients. Information collected as part of this initiative will be used to develop future policy options. Furthermore, PGD-specific data may be beneficial to the Committee as it develops a continuous distribution allocation framework, which is expected to begin in early 2023. This document presents the transplant community with an opportunity to discuss and provide feedback on the information that should be considered for a future data collection proposal.

A Subcommittee was created to address the majority of the work, and tasked with defining the project's scope and identifying potential data elements. It was determined that obtaining community feedback would help them identify the best data elements to consider. As a result, the members developed this Request for Input document as a way to gather such information during the January-March, 2021 public comment cycle. The OPTN Data Advisory Committee was engaged and was told how the project aligns with the OPTN Data Collection Principles and the standard of review checklist. The Heart Committee is approaching the project in two phases; this initial request for input, and a presumed subsequent data collection proposal.

Suggested Data Elements

Based on previous discussions, the Committee is seeking feedback on the following data elements that could potentially be collected on the Transplant Recipient Registration (TRR) form to capture information about PGD. In addition, the Committee is seeking the community's feedback regarding how soon after the transplant the information should be collected. The Committee members decided to include more data elements than just those identified in the ISHLT consensus statement. They agreed that additional elements are needed in order to capture changes in clinical practice and research findings since the consensus statement was released in 2013.

PGD related data elements for assessing associated transplant mortality

The data elements the Committee selects will establish how detailed the future monitoring activities can be. However, the Committee also needs to consider how transplant programs will be impacted by the types of information requested and the volume of data elements that must be reported. The Committee also faces challenges when determining the level of detail to collect about treatments.

The Committee suggests collecting the data elements from all heart transplant recipients at an early time point following transplant. Programs will be asked to provide clinical values for certain PGD-related data. **Table 1 on the following page** reflects the data elements the Committee initially identified. The members chose these elements as if they would pursue an expansive data collection effort. The table also shows the values or ranges associated with the data elements.

In addition to these data elements identified for collection, Body Surface Area will be calculated based on the Dubois method using the entries transplant program staff provide for height and weight and will be measured in meters^2.

Table 1: Potential Data Elements for Addition to the Transplant Recipient Registration Form (TRR) Associated with Primary Graft Dysfunction (PGD)

Data Element	Values and/or Range
Primary Graft Dysfunction	Yes or no
Left Ventricular Dysfunction	Yes or no
Right Ventricular Dysfunction	Yes or no
Left Ventricular Ejection Fraction	Percentage
Right Atrial Pressure (RAP)	mm Hg
Pulmonary Capillary Wedge Pressure (PCWP)	mm Hg
Pulmonary Artery Systolic Pressure Pulmonary Artery Diastolic Pressure	mm Hg
Cardiac Output[b]	L / min
Support device	Yes or no
If yes to support device	Right, left, or biventricular
Type of device[c]	Drop down list of devices
Inotrope support	Drop down list of drugs (Multiple selections of drug types are acceptable) Dosings (Exact doses or dose ranges)

[a] PGD refers to graft dysfunction occurring immediately after transplant, requiring greater than typical medical support, or mechanical support. PGD is graft dysfunction not attributable to hyperacute rejection, acute rejection, antibody mediated rejection, surgical implant issues, or acute infarction.
[b] Reported cardiac output will be used to calculate cardiac index in UNet℠.
[c] See **Appendix B** for the list of support devices.

The Committee also seeks community feedback regarding the challenges associated with properly capturing PGD. Would programs be able to record vasoactive drug dosages or would a range of dosages be preferable? Should support devices used pre-transplant and continued post-transplant be excluded? The Committee also seeks community feedback regarding collection of data pertaining to the use of pre-transplant therapies that may increase the risk of PGD. While procurement type is included, there are other data elements, such as warm ischemia time, that are not currently collected and may be associated with PGD. Currently, OPTN data includes total ischemic time as a calculated field. Collecting warm ischemia time could be a large challenge for the heart transplant community to identify the appropriate time points and actions within the process.

Defining the timeframe following transplant for data collection

The Committee seeks community feedback regarding when a transplant program should collect PGD information. Monitoring and reporting activities involving PGD-related information will require that the data be collected shortly following transplant, contrasted to current follow-up forms that collect information six months or annually after transplant.

The Committee members discussed different data collection points following the transplant procedure. For example, some members stated that the information should be collected at 24 hours post-procedure, in part because the ISHLT consensus statement requires that a PGD diagnosis be made within that timeframe. Other members countered that a recipient may still be recovering from the surgical impacts at 24 hours. In such cases, it may be difficult to single out PGD from other complications. To address this, some members recommended data collection occur at 72 hours after transplant, or within 72 hours following transplant. This timeframe would be similar to that employed in the Lung TRR forms to collect lung-related PGD data. If data are to be collected within 72 hours, the Committee members discussed whether transplant programs should report the lowest or highest value recorded during the timeframe. The Committee seeks community feedback about the timeframes.

The Committee is also requesting feedback as to the appropriateness of permitting the medical team caring for the patient to determine the postoperative timeframe of hemodynamic and vasoactive medications. Potential postoperative options include: in the operating room; first day in the Intensive Care Unit (ICU), second day in the ICU, etc. Should the worse hemodynamic measurements and highest doses of medications be recorded or should it be at a specific time point?

Consideration of risk factors as potential data elements for collection

The Committee seeks feedback from the community about whether to collect new predictive and operational data elements, potentially associated with PGD, such as details of organ preservation procedure, and warm ischemia time. The members request input as to whether such information would be useful when monitoring outcomes in the future or for assisting with future policy development decisions.

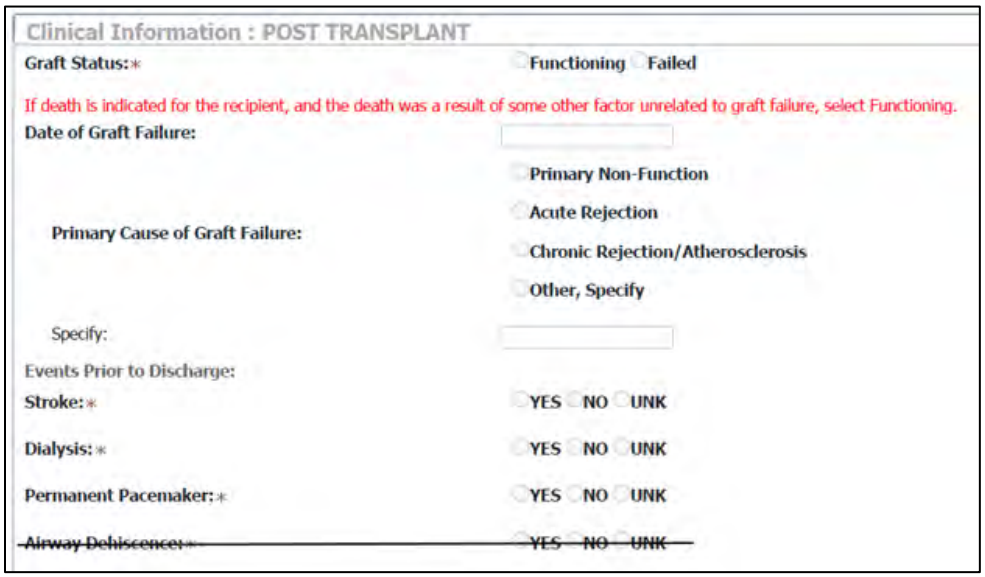
The Committee members discussed that while the type of perfusion solution is collected currently through OPTN data submission, the amount of solution nor the presence or absence of backpressure is not. The amount of solution used may be helpful in identifying if PGD has occurred or if another complication is present.

The Committee also requests community input about factors associated with procurement as potential data elements. The factors could include whether the organ was procured by a team from the donor hospital or a team from the transplant program, as well as cold, and warm ischemia times. The Deceased Donor Registration (DDR) form collects the data elements: Clamp Date, Clamp Time, and Clamp Time Zone, which are used to determine when cold ischemia time begins. The Committee is also interested in the warm ischemia time associated with hearts procured related to Donation after Cardiac Death (DCD). The heart transplantation community is asked to comment on the advantages and disadvantages associated with collecting warm ischemia time. Furthermore, the Heart Committee requests input to identify the most important time points for collecting warm ischemia information. These might include steps in the process such as removal from cold storage, first anastomosis, and/or reperfusion.

Consideration of eliminating data elements from the Heart-related collection forms

Exhibit 1 shows the post-transplant clinical information currently collected on the adult heart Transplant Recipient Registration (TRR) form. The Committee identified "Airway Dehiscence" for potential removal from the heart TRR because it is not relevant to heart transplants. The Committee also discussed the relevance to heart transplantation of the options included with the Primary Cause of Graft Failure," and whether additional options should be included. The Committee is requesting the community's feedback concerning the removal of airway dehiscence, and the primary causes of graft failure.

Exhibit 1: Adult Heart Transplant Recipient Registration Form



Source: Heart Transplant Recipient Registration form.

NOTA and Final Rule Analysis

The Request for Input intends to gather feedback from the community about PGD data collection. The document is an initial step towards an official data collection proposal in the future. The Committee submits this Request for Input for consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall…submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs..."[21] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients."[22] This Request for Input will help the Committee's consideration of PGD-related data elements to recommend for future collection on heart transplant recipients.

[21] 42 CFR §121.11(b)(2).
[22] 42 CFR §121.11(a)(1)(ii).

Implementation Considerations

Member and OPTN Operations

While the document is only requesting feedback, the operations of the transplant programs, OPOs, histocompatibility labs, and the OPTN should not be affected. At the same time, the Committee encourages feedback describing how the proposed new data collection may cause operational concerns within the transplant community.

Project Fiscal Impact

Minimal or no expected fiscal impact for transplant hospitals, OPOs, or histocompatibility labs. Likewise, there is minimal or no expected fiscal impact for the OPTN. The Committee requests input from the transplant community as to the whether the proposed new data collection would result in a fiscal impact to OPTN members.

Summary

Primary Graft Dysfunction has a substantial effect on the morbidity and mortality of heart transplant recipients. The intent of this request for input is to solicit community feedback on a specific set of new data elements and data-related questions which will help the Committee as it develops a future PGD data collection proposal. The new data elements the Committee is proposing are not currently collected by the OPTN. The Committee knows that several years of data collection may be necessary before there will be enough data for an appropriate analysis, and to promote informed discussions and decisions regarding potential policy development.

The Committee is requesting feedback about the following:

Data elements and timing

- What, if any, data elements should be included?
- Is it appropriate to focus on moderate to severe PGD? Or, should only severe PGD requiring mechanical support be collected?
- How many hours following completion of the transplant should the data be collected? (When should the data be collected? For example, arrival in ICU? 24 hours? 72 hours? Another time?)
- Should the Committee collect an expansive or narrow amount of data?
- What, if any, left ventricular assist device (LVAD)-related information should be collected that would benefit a review of primary graft dysfunction? (How can that information be collected in the most consistent, straightforward way possible?)
- What information should be collected and reported about Donation after Cardiac Death (DCD) donors that could help the Committee better consider the impact of such donors on the incidence of PGD?

Other

- What challenges would this request present for transplant programs responsible for collecting the additional data?

- Do transplant programs have the necessary information to report this data?
- Is the Transplant Recipient Registration (TRR) form the correct data collection tool to use?
- Should the data collection be part of the “Clinical Information: POST TRANSPLANT” section of the TRR, or is there a more appropriate section?
- Are there differences and/or similarities between adult and pediatric PGD the Heart Committee should consider as part of its future reviews?
- How can the Committee ensure the data collection is reported consistently by all transplant programs?
- Do Organ Procurement Organizations have the necessary information about DCD donors that would benefit this project?

Appendix A: ISHLT Consensus Statements on Primary Graft Dysfunction (PGD) and Definition of Severity Scale for PGD

Consensus Statements

1. Graft dysfunction is to be classified into PGD or secondary graft dysfunction where there is a discernible cause such as hyperacute rejection, pulmonary hypertension, or known surgical complications (e.g., uncontrolled bleeding).
2. The diagnosis of PGD is to be made within 24 hours after completion of the cardiac transplant surgery.
3. PGD is to be categorized into PGD-LV or PGD-RV.
4. A severity scale for PGD-LV will include mild, moderate or severe grades based on specified criteria.
5. Risk factors are categorized in terms of donor, recipient, or surgical procedural factors. Optimization of risk factors and improved allocation and matching of donors and recipients may result in decreased incidence of PGD.
6. Medical management with inotropic support should initially be instituted for PGD. The use of levosimendan may also be helpful. For PGD-RV, nitric oxide and phosphodiesterase inhibitors may be helpful.
7. Mechanical circulatory support of PGD such as ECMO is indicated when medical management is not sufficient to support the newly transplanted graft.
8. Retransplantation for severe PGD may be indicated in select patients if risk factors are minimal.
9. All patients in whom mechanical circulatory support is placed directly into the heart should have a biopsy performed at that time.
10. It was recommended that an autopsy should be performed in all patients who are diagnosed with PGD and subsequently expire.
11. Potential future studies include creation of a PGD registry, impact of preservation solutions on PGD, mechanistic studies to understand pathophysiology of PGD, and study of donor management to minimize PGD, among others.

Definition of Severity Scale for Primary Graft Dysfunction (PGD)

1. PGD Left ventricle (PGD-LV):	*Mild PGD-LV*: *One* of the following criteria must be met:	LVEF ≤ 40% by echocardiography, *or* Hemodynamics with RAP > 15 mm Hg, PWCP > 20 mm Hg, CI < 2.0 L/min/m^2 (lasting more than 1 hour) requiring low-dose inotropes
	Moderate PGD-LV: Must meet one criterion from I *and* another criterion from II:	I. *One* criteria from the following: Left ventricular ejection fraction ≤ 40%, *or* Hemodynamic compromise with RAP > 15 mm Hg, PCWP > 20 mm Hg, 20 mm Hg, CI < 2.0 L/min/m^2, hypotension with MAP < 70 mm Hg (lasting more than 1 hour) II. *One* criteria from the following: i. High-dose inotropes—Inotrope score > 10[a] or ii. Newly placed IABP (regardless of inotropes)
	Severe PGD-LV	Dependence on left or biventricular mechanical support including ECMO, LVAD, BiVAD, or percutaneous LVAD. Excludes requirement for IABP.
2. PGD-right ventricle (PGD-RV):	Diagnosis requires either both I and ii, or iii alone:	i. Hemodynamics with RAP > 15 mm Hg, PCWP < 15 mm Hg, CI < 2.0 L/min/m^2 ii. TPG < 15 mm Hg and/or pulmonary artery systolic pressure < 50 mm Hg, *or* iii. Need for RVAD

BiVAD, biventricular assist device; CI, cardiac index; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; PCWP, pulmonary capillary wedge pressure; RAP, right atrial pressure; RVAD, right ventricular assist device; TPG, transpulmonary pressure gradient.

[a] Inotrope score = dopamine (x1) + dobutamine (x1) + amrinone (x1) + milrinone (x15) + epinephrine (x100) + norepinephrine (x100) with each drug dosed in µg/kg/min.

Source: Kobashigawa, Jon, Zuckermann, Andreas, Macdonald, Peter, Leprince, Pascal, Esmailian, Fardad, Luu, Minh, Mancini, Donna, Patel, Jignesh, Razi, Rabia, Reichenspurner, Hermann, Russell, Stuart, Segovia, Javier, Smedira, Nicolas, Stehlik, Josef, and Wagner, Florian. "Report from a Consensus Conference on Primary Graft Dysfunction after Cardiac Transplantation." *The Journal of Heart and Lung Transplantation* 33, no. 4 (2014): 337-38.

Appendix B: List of Mechanical Circulatory Support Devices Associated with Certain Adult Heart Statuses

Dischargeable VADs	Non-Dischargeable VADs	Percutaneous Devices	Total Artificial Hearts
Evaheart	Abiomed AB5000	Biomedicus	AbioCor
Heartmate II	Abiomed BVS 5000	Cardiac Assist Tandem Heart	SynCardia CardioWest
Heartmate III	Berlin Heart EXCOR	Cardiac Assist Protek Duo	Other Specify
Heartsaver VAD	Biomedicus	CentriMag (Thoratec/Levitronix)	—
Heartware HVAD	CentriMag (Thoratec/Levitronix)	Impella Recover 2.5	—
Jarvik 2000	Maquet Jostra Rotaflow	Impella Recover 5.0	—
ReliantHeartAssist 5	Medos	Impella CP	—
ReliantHeart aVAD	PediMag (Thoratec/Levitronix)	Impella RP	—
Worldheart Levacor	Terumo Duraheart	Maquet Jostra Rotaflow	—
Other Specify	Thoratec IVAD	PediMag (Thoratec/Levitronix)	—
—	Thoratec PVAD	Other Specify	—
—	Toyobo	—	—
—	Ventracor VentrAssist	—	—
—	Other Specify	—	—

Notes: There are no device brands for Venoarterial Extracorporeal Membrane Oxygenation (VA ECMO) or Intra-aortic Balloon Pump (IABP). The “Other Specify” category is included for instances where a candidate’s device brand is not identified.
Source: OPTN website (accessed on November 8, 2020): https://optn.transplant.hrsa.gov/media/2457/heart_device_brand_background.pdf

OPTN

Public Comment Proposal

Clarify Multi-Organ Allocation Policy

OPTN Organ Procurement Organization Committee

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Clarify Multi-Organ Allocation Policy

Affected Policies:	*5.10.C: Allocation of Kidney-Pancreas* *5.10.D: Allocation of Liver-Intestines* *5.10.E: Other Multi-Organ Combinations* *8.7.C: Kidney Allocation in Multi-Organ Combinations* *8.7.D: Multi-Organ Combinations Allocated but Not Transplanted* *8.7.E: Location of Donor Hospitals* *9.9: Liver-Kidney Allocation*
Sponsoring Committee:	*Organ Procurement Organization*
Public Comment Period:	*January 21, 2021 – March 23, 2021*

Executive Summary

Multi-organ allocation policies have been an area of concern for many years. The OPTN Ethics Committee developed a white paper to provide guidance on multi-organ transplant policy and practice.[1] The Board of Directors approved this white paper in June 2019. In 2019, the OPTN Policy Oversight Committee (POC) began developing strategic policy priorities. One of the priorities identified and approved by the OPTN Executive Committee was to improve equity for multi-organ and single organ candidates.[2] A multi-disciplinary workgroup was formed to begin addressing multi-organ allocation policies.[3]

This proposal addresses the first step of this strategic policy priority by clarifying OPTN *Policy 5.10.C: Other Multi-Organ Combinations*. The current policy addresses multi-organ combinations for candidates on the heart, lung, or liver waiting list that require a second organ. Current policy does not address which match run is used or provide specifics about the "second required organ." This leads to inconsistent application of the requirements outlined in this policy.

The OPO Committee proposes criteria for when OPOs are required to offer the liver or kidney, if available, from the same donor. For heart candidates, the criteria will include adult status 1, 2, and 3 and pediatric 1A and 1B. For lung candidates, the criteria will include candidates with a lung allocation score of greater than 35. Additionally, the proposed distance for this mandatory offer will be increased from the current 150 nautical miles (NM) for liver and 250 NM for heart and lung to a 500 nautical miles circle to better align with thoracic allocation policies.

This proposal addresses heart-liver, lung-liver, heart-kidney, and lung-kidney multi-organ combinations. This proposal establishes requirements for when OPOs must offer the liver or kidney when allocating according to the heart or lung match run.

[1] https://optn.transplant.hrsa.gov/media/2801/ethics_publiccomment_20190122.pdf
[2] https://optn.transplant.hrsa.gov/media/3615/20191008_exec_comm_summary.pdf
[3] https://optn.transplant.hrsa.gov/media/3005/201906_board_executivesummary.pdf

Background

In 2019, the OPTN Policy Oversight Committee (POC) began developing strategic policy priorities. The criteria for strategic policy priorities included the following:

- Impact to multiple organ systems
- Impact to multiple member types
- Require expertise from multiple committees and stakeholder organizations
- Require changes to multiple policies to provide consistent approach
- Results in large-scale improvement to deliver the greatest benefit to the community.

One of the priorities identified and approved by the OPTN Executive Committee was to improve equity for multi-organ and single organ candidates. The initial step in a phased approach to address multi-organ policies is to revise the general multi-organ policy prior to beginning work on any specific multi-organ policies. This will ensure that the specific multi-organ policies are consistent with the general multi-organs policy. The next phase of this effort will be to address other multi-organ combinations, with eligibility criteria for heart-kidney identified as the next step.

OPTN Policy 5.10.C: Other Multi-Organ Combinations was modified as part of several recent proposals that removed donation service area (DSA) from heart, lung, and liver allocation policies.[4,5] These changes replaced DSA with 150 nautical miles (NM) for liver and 250NM for lung and heart as the distances for when the OPO is required to offer the second required organ. The intent of these changes was to remove DSA from allocation policy, not to provide new requirements for OPOs when allocating multi-organ combinations. Current policy requires a certain level of interpretation by OPOs, which can lead to inconsistent practice across the country.

While the number of multi-organ combinations not currently addressed in policy are relatively small as illustrated in **Figure 1**, it is important for the Committee to address the combinations in this proposal as part of the phased approach to addressing multi-organ policies. Addressing heart-liver, lung-liver, heart-kidney, and lung-kidney combinations will address 84% of the combinations not currently addressed in other policies.

[4] https://optn.transplant.hrsa.gov/media/2994/thoracic_boardreport_201906.pdf - or *OPTN Thoracic Organ Transplantation Committee Report to the Board of Directors*, OPTN Thoracic Organ Transplantation Committee, June 2019.
[5] https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf or *OPTN Liver and Intestinal Organ Transplantation Committee Report to the Board of Directors*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018.

Figure 1: Number of Multi-Organ Transplants (2016-2019)

Multi-Organ Transplants					
	2016	2017	2018	2019	Policy?
All deceased donor transplants	27,630	28,588	29,680	32,322	
All Multi-Organ Transplants	1801	1853	1882	1989	
Liver-Kidney	730	739	677	727	Yes
Kidney-Pancreas	798	789	835	872	Yes
Heart-Kidney	140	187	203	219	No
Liver-Intestine-Pancreas	58	55	51	35	No
Liver-Heart	18	29	39	45	No
Heart-Lung	18	29	32	45	Yes
Liver-Lung	9	8	14	12	No
Intestine-Pancreas	8	3	4	5	No
Kidney-Intestine	5	1	2	3	No
Kidney-Lung	4	7	9	13	No
Liver-Pancreas	3	1	2	1	No
Liver-Intestine	2	0	3	1	Yes
Liver-Kidney-Heart	1	0	3	6	No
Liver-Kidney-Intestine-Pancreas	7	2	7	4	No
Kidney-Heart-Lung	0	2	2	1	No
Liver-Pancreas-Lung	0	0	0	0	No
Liver-Kidney-Pancreas	0	0	0	0	No
Kidney-Intestine-Pancreas	0	0	0	0	No
Liver-Kidney-Intestine	0	0	0	0	No
Heart-Pancreas	0	0	0	0	No
Liver-Heart-Lung	0	1	0	0	No
https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/					

A multi-disciplinary workgroup (Workgroup) was formed with representation from the following OPTN committees:

- Organ Procurement Organization
- Liver and Intestinal Organ Transplantation
- Heart Transplantation
- Lung Transplantation
- Kidney Transplantation
- Pancreas Transplantation
- Pediatric Transplantation
- Transplant Coordinators
- Vascular Composite Allograft
- Ethics
- Patient Affairs

Purpose

The purpose of this proposal is to provide OPOs with clearer direction when offering multi-organ combinations by establishing criteria for when OPOs must offer the liver or kidney to heart or lung candidates listed for these organs.

The OPO Committee submits the following proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing….policies for the equitable allocation of cadaveric organs"[6] and "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[7]

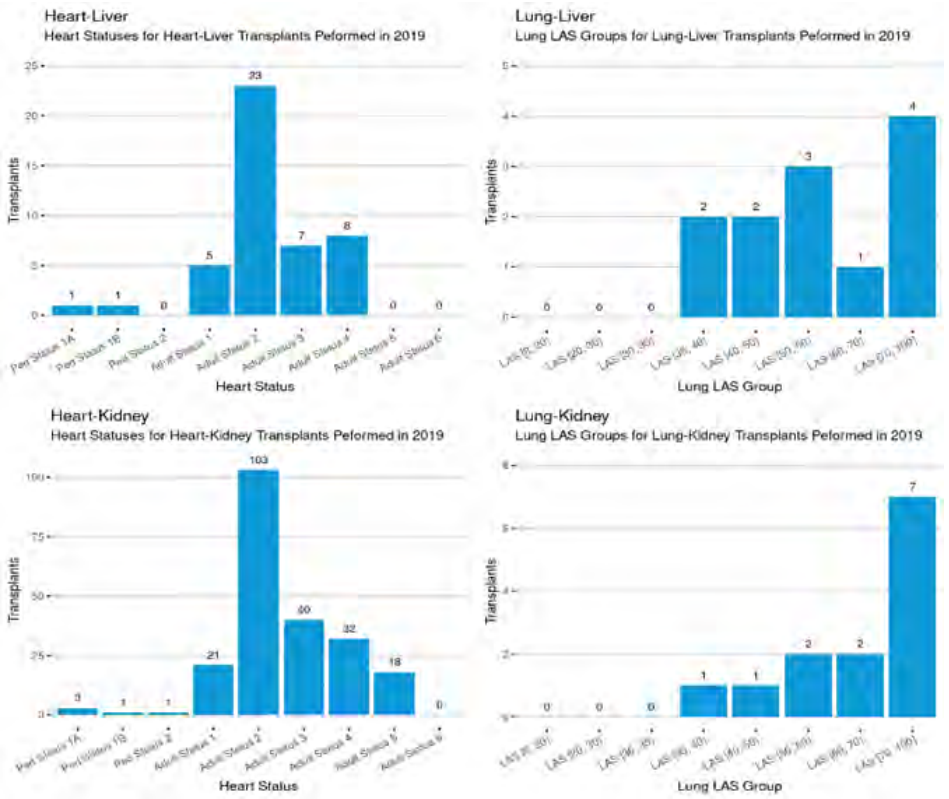
Overview of Proposal

The OPO Committee proposes adding medical criteria and increasing the distance for heart and lung candidates that require a second organ. The criteria will establish requirements for when OPOs must offer the second organ to the same candidate when allocating according to either the heart or lung match run. The Committee is also proposing clarity that the heart and lung match runs will drive the allocation of these combinations.

Heart and Lung Multi-Organ Criteria

The workgroup reviewed data on the statuses of multi-organ candidates who received heart-liver, lung-liver, heart-kidney, or lung-kidney transplants in 2019.[8] **Figure 2** shows the recipient statuses for these combinations of multi-organ transplants.

Figure 2: Recipient Statuses at Transplant (2019)



[6] 42 CFR §121.8(a)
[7] 42 CFR §121.8(a)(4)
[8] See Multi-Organ Policy Workgroup Meeting Summary, May 29, 2020. Available at https://optn.transplant.hrsa.gov/

The Committee proposes the following criteria for heart and lung candidates to receive offers for either a kidney or liver, if listed for a second organ:

- Heart Adult Status 1, 2, and 3, Pediatric Status 1A and 1B
- Lung Candidates with a lung allocation score of greater than 35

The statuses were determined based on the data shown in **Figure 2**. The higher status heart and lung candidates are admitted to the hospital, as required in *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.

For multi-organ transplants performed in 2019, the following multi-organ transplants would meet the proposed criteria:

- Heart-liver transplants - 37 of 45
- Heart-kidney – 169 of 219
- Lung-liver – 12 of 12
- Lung-kidney – 13 of 13

Several workgroup members were concerned about disadvantaging liver and kidney alone candidates if livers or kidneys are placed with heart or lung candidates listed for a second organ. It is important to note that the current policy does not prioritize multi-organ candidates over single organ candidates. Even with the proposed changes, OPOs will still be required to allocate organs according to current *Policy 2.2: OPO Responsibilities*, which states that OPOs execute the match run and use "the resulting match for each deceased donor allocation."

As referenced in the Ethics Committee white paper, Reese et al. outlined the challenges of identifying candidates who most benefit from a multi-organ transplant while also trying to avoid undermining utility (defined as optimal patient and graft survival).[9] For example, a heart status 1 candidate might receive the liver from the same donor regardless of model for end-stage liver disease (MELD) score when there is a higher status liver alone candidate in need of a liver transplant. Further complicating the issue is the difficulty in trying to evaluate such a small population of candidates. Goldberg et al. found that "although transplant is delayed, liver transplant waitlist candidates bypassed by heart-liver recipients do not have excess mortality compared to three sets of matched controls."[10]

Another consideration is the biological disadvantage of heart and lung candidates. Donor-recipient height, weight and gender matching are important factors in post-transplant outcomes. While recent publications, such as Eberlein et al., recommend changes to how thoracic organ sizes are measured, "donor-to-recipient organ size matching is a critical aspect of thoracic transplantation."[11] This can limit the number of offers that heart and lung candidates can accept and further impact those candidates needing a liver or kidney. This contributed to the decision to establish criteria for heart and lung candidates.

[9] Reese P, Veatch RM, Abt PL, and Amaral S. Revisiting Multi-Organ Transplantation in the Setting of Scarcity. *American Journal of Transplantation* 14, no. 1 (2013): 21-26. doi:10.1111/ajt.12557.
[10] Goldberg DS, Reese PP, Amaral S, Abt PL. Reframing the Impact of Combined Heart-Liver Allocation on Liver Transplant Waitlist Candidates. *Liver Transplantation*. 2014 November; 20(11): 1356–1364. doi:10.1002/lt.23957.
[11] Eberlein M, Reed RM. Donor to recipient sizing in thoracic organ transplantation. World Journal of Transplantation, 2016 March 24; 6(1): 155-164

The Committee believes that establishing criteria that provides access to the second organ for sicker heart and lung candidates aligns with current practice as the community awaits further work on eligibility criteria and safety nets for multi-organ allocation. The intent of this proposal is to provide clearer rules for OPOs when allocating a heart or lung according to the match run and a heart or lung candidate is listed for a liver or kidney. This proposal also allows OPOs the discretion to determine the best approach to placing organs according to OPTN policy, even if multi-organ candidates do not meet the criteria in this proposal.

Reference to Kidneys

Currently, *Policy 5.10.C: Other Multi-Organ Combinations* does not reference kidneys as the second required organ that must "be allocated to the multi-organ candidate from the same donor" within the geographic areas outlined in the policy. However, *Policy 9.9: Liver-Kidney Allocation* addresses the requirements for OPOs when a kidney is procured along with other organs. The OPO must first offer the kidney according to *Policies 5.10.C*, *9.9*, or *11.4.A: Kidney-Pancreas Allocation* before allocating to kidney alone candidates. This proposal does not affect an OPO's ability to decide which multi-organ policy to utilize when a kidney is procures with other organs.

The Committee agreed that it is common practice for OPOs to allocate the kidney from the same donor if a heart or lung candidate on the match run is also listed for a kidney. The absence of clear requirements in the current policy leads to inconsistent application of the rules. Therefore, the Committee proposes adding specific language addressing kidneys as part of heart-kidney and lung-kidney combinations. The Committee recognizes the impact that allocating kidneys to multi-organ candidates have on kidney alone candidates. A recent publication by Westphal et al. highlighted "the potential for multi-organ transplant prioritization to unintentionally introduce disparities in transplant access for kidney alone candidates."[12] This further underscores the importance of addressing multi-organ allocation policies in an era where the need outnumbers the supply.

The Committee acknowledges that this effort clarifies current policy but does not address medical eligibility criteria or a "safety net" as used in current simultaneous liver kidney (SLK) policy. The Committee is committed to clarifying current policy while working with stakeholders across the community during the impending effort to pursue these additional policies.

Change to Geographic Unit

The Committee is proposing changes to the distances outlined in current policy. The current distance is 250 nautical miles (NM) for heart and lung and 150 NM for liver, which are the smallest units of allocation for heart, lung, and liver. These distances were established when liver and thoracic policies changed from donation service area (DSA) to distance-based distribution.[13,14,15]

[12] Westphal, S. G., Langewisch, E. D., Robinson, A. M., Wilk, A. R., Dong, J. J., Plumb, T. J., Mullane, R., Merani, S., Hoffman, A. L., Maskin, A., & Miles, C. D. (2020). The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 10.1111/ajt.16390. Advance online publication. https://doi.org/10.1111/ajt.16390
[13] https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf
[14] https://optn.transplant.hrsa.gov/media/3003/thoracic_policynotice_201906.pdf
[15] https://optn.transplant.hrsa.gov/media/2539/thoracic_policynotice_201807_lung.pdf

The Committee proposes increasing the distance to 500 NM to better align with current heart allocation. This will allow the candidates with the proposed statuses to access a liver or kidney if needed. For example, the classifications for Status 1 and 1A heart candidates start at 500NM according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old* and *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.

The Committee also proposes 500 NM for lung candidates in order to be consistent within the proposed policy. The allocation of lungs from donors at least 18 years old begins with 250 NM for classifications 1-6 followed by 500 NM for classifications 7-12.[16] The allocation of lungs from donors less than 18 years of age begins with 1000 NM, which presents more logistical challenges when allocating multi-organ combinations. However, the proposed distance of 500 NM does not prevent OPOs from having the discretion to place a kidney or liver with a candidate outside the 500 NM circle.

Clarity on Match Runs

The current policy provides little direction for OPOs regarding which match run to use when allocating multi-organ combinations. While this proposal does not establish OPO requirements for which organs must be allocated first, it does provide clarity that OPOs allocating according to the heart or lung match run must offer the liver or kidney to a candidate listed for the second organ if they meet the proposed criteria. The criteria based on proposed medical urgency and 500NM will determine when the OPO must offer the second organ. This proposal does not mandate which match run to start with – therefore allowing for OPO discretion.

Other Considerations

The multi-disciplinary workgroup discussed creating policies to require OPOs to allocate organs to higher status kidney or liver alone candidates if no higher status heart or lung candidates required a second organ. This would be required before allocating the second organ to other multi-organ candidates that do not meet the proposed criteria.

There are several challenges to creating such policy requirements. There is a lack of consistency in organs available per donor as well as the quality of organs. Additionally, there are multiple considerations for how proposed changes may affect other OPTN policies. For example, establishing a mandate that OPOs allocate to kidney alone candidates prior to other multi-organ candidates would need to align with kidney-pancreas or simultaneous liver-kidney policies.

The Committee ultimately decided not to move forward with policy requirements to address the examples shown above. The various multi-organ scenarios discussed by the Committee outlined the challenges in developing a multi-organ policy that provides clear rules for OPOs. The Committee acknowledges that this proposal is an important step forward in MOT policy, but does not address all of multi-organ combinations. The Committee is committed to working with stakeholders across the community to continue to address multi-organ allocation policies. The next phase of this effort will address other multi-organ combinations, with eligibility criteria for heart-kidney identified as the next step.

[16] OPTN Policy 10, Allocation of Lungs (April 15, 2020)

Additional Policy Changes

As the OPTN moves forward with future multi-organ policy changes, it might be beneficial to the transplant community to consolidate multi-organ policies into one location. Therefore, as a first step, the Committee proposes several non-substantive policy modifications.

Policy 5.10: Allocation of Multi-Organ Combinations currently includes the following sections:

- *Policy 5.10.A: Allocation of Heart-Lungs*
- *Policy 5.10.B: Allocation of Liver-Kidneys*
- *Policy 5.10.C: Other Multi-Organ Combinations*.

The first two sections provide references to heart-lung and liver-kidney policies and do not contain substantive policy requirements. The Committee proposes two new policy sections, *5.10.C: Allocation of Kidney-Pancreas* and *5.10.D: Allocation of Liver-Intestines* that will reference kidney-pancreas and liver-intestine policies and serve as placeholders for future consolidation of multi-organ policies. Below is the proposed structure for *Policy 5.10: Allocation of Multi-Organ Committee*:

5.10: Allocation of Multi-Organ Combinations

- *5.10.A: Allocation of Heart-Lungs*
- *5.10.B: Allocation of Liver Kidneys*
- *5.10.C: Allocation of Kidney-Pancreas*
- *5.10.D: Allocation of Liver-Intestines*
- *5.10.E: Other Multi-Organ Combinations*

Additional changes include relocating policy language from *Policy 9.9: Liver-Kidney Allocation* to kidney policy. The rationale for this change is that the policy language focuses on kidney allocation as part of multi-organ combinations. This change will not affect liver-kidney allocation policy.

Next Steps

As stated in the previous sections, this proposal by the Committee is the first step in a long-term effort and strategic policy priority by the Policy Oversight Committee (POC). The OPO Committee will collaborate with clinical and organ-specific committees in the coming efforts to further address other multi-organ OPTN policies to ensure efficient and equitable access to transplant for multi-organ and single-organ candidates.

NOTA and Final Rule Analysis

The OPO Committee submits this proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing….policies for the equitable allocation of cadaveric organs"[17] and "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[18]

[17] 42 CFR §121.8(a)
[18] 42 CFR §121.8(a)(4)

The Final Rule requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment:**[19] The Committee proposes this change based on the medical judgment of OPO professionals, transplant surgeons, and members of eleven stakeholder committees in deriving the proposed changes. The Committee's recommendations were informed by reviews of OPTN data and peer review literature.
- **Is designed to avoid wasting organs:**[20] The Committee believes this proposal will decrease the number of organs recovered but not transplanted, which maximizes the gift of organ donation by using each donated organ to its full potential. This proposal seeks to avoid organ loss by ensuring clear rules for allocating multi-organ combinations while also allowing OPOs the flexibility to make discussions related to organ placement.
- **Shall be designed to…to promote the efficient management of organ placement:**[21] This proposal provides clear rules for when to offer the second organ with the heart or lung. This reduces inconsistent application created by the current policy language.

This proposal also preserves the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[22] and it is specific to various combinations of organ types.[23]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- This proposal is not based on a candidate's place of residence or place of listing

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[24] The Committee did not identify any populations may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors, and does not recommend any particular transition procedures.

[19] 42 CFR §121.8(a)(1)
[20] 42 CFR §121.8(a)(5)
[21] 42 CFR §121.8(a)(5)
[22] 42 CFR §121.8(a)(3)
[23] 42 CFR §121.8(a)(4)
[24] 42 CFR §121.8(d)

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

OPOs will continue allocating donor organs according to the heart and lung match runs. OPO staff will need to be aware of the new requirements for when the liver or kidney is offered to a heart or lung potential transplant recipient.

Operations affecting Transplant Hospitals

Transplant programs may be impacted by the change to 500NM for heart and lung candidates who need either a liver or kidney. In practice, transplant programs receiving offers for both organs should evaluate the logistics and work with the host OPO to facilitate placement.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories

Operations affecting the OPTN

This proposal will require programming in UNet^{SM} to include a visual indicator on the organ match runs to display candidates who meet the requirements for multi-organ allocation. This is meant to aid the OPO in determining if multi-organ allocation requirements have been met prior to offering the second required organ. Proposed programming does not require approval from the federal Office of Management and Budget (OMB).

Potential Fiscal Impact of Proposal

OPOs

Policy and programming changes associated with this proposal adds efficiency and consistency across systems because it creates a better organ matching system. Current workflow varies at each OPO for multi-organ allocation, but minimal effort is needed to adjust and create these efficiencies.

Transplant Hospitals

There is no or minimal expected fiscal impact for transplant hospitals.

Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

Preliminary estimates indicate that this will be a medium effort, as over 700 hours may be needed for IT programming, communication, educational efforts, and post-implementation monitoring.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[25]

The proposed language will not change the routine allocation monitoring of OPTN members. The OPTN will continue to review all deceased donor match runs that result in a transplanted organ and will continue to investigate potential policy violations.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[26] This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data to UNet℠) and compared to an appropriate pre-implementation cohort.

For heart-liver, heart-kidney, lung-liver, and lung-kidney:

- Number of multi-organ transplants
    - Stratify by required vs permissible share
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - Stratify by distance from donor hospital to transplant center
    - By OPTN Region
- Number of deaths on the waiting list for multi-organ candidates
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - By OPTN Region
- Waitlist volumes for multi-organ candidates
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - By OPTN Region

Conclusion

This proposal addresses the initial phase of the POC strategic policy priority to address multi-organ policies by clarifying OPTN *Policy 5.10.C: Other Multi-Organ Combinations*. The OPO Committee proposes criteria for when OPOs are required to offer the liver or kidney, if available, from the same donor. For heart candidates, the criteria will include adult status 1, 2, and 3 and pediatric 1A and 1B. For lung candidates, the criteria will include candidates with a lung allocation score of greater than 35.

[25] 42 CFR §121.8(a)(7)
[26] 42 CFR §121.8(a)(6)

Additionally, the proposed distance for this mandatory offer will be increased from the current 150 nautical miles (NM) for liver and 250 NM for heart and lung to a 500 nautical miles circle to better align with thoracic allocation policies.

The Committee is also proposing additional policy changes as the initial step towards consolidating multi-organ allocation policies.

The Committee proposes these policy changes to promote efficient and equitable allocation for these multi-organ combinations. This proposal is a continuation of previous efforts and builds a foundation for the continued work within the strategic policy priority to address multi-organ allocation policies.

The Committee encourages all interested individuals to comment on this proposal in its entirety, but specifically asks for feedback on the following:

1. Is Heart Adult Status 1, 2, 3 and Pediatric Status 1A and 1B appropriate thresholds for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?
2. Is a lung allocation score of greater than 35 an appropriate threshold for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?
3. Is 500 NM an appropriate distance for when OPOs must offer a liver or kidney to a multi-organ candidate meeting the proposed criteria?
4. Do you believe all multi-organ policies should be located in the same section of policy?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

5.10 Allocation of Multi-Organ Combinations

5.10.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.6.F: Allocation of Heart-Lungs*.

5.10.B Allocation of Liver-Kidneys

Liver-kidney combinations are allocated according to *Policy 9.9: Liver-Kidney Allocation*.

5.10.C Allocation of Kidney-Pancreas

Kidney-pancreas combinations are allocated according to *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets.*

5.10.D Allocation of Liver-Intestines

Liver-intestine combinations are allocated according to *Policy 9: Allocation of Livers and Liver-Intestines*

5.10.E Other Multi-Organ Combinations

~~When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to *Table 5-4.*~~

~~**Table 5-4**~~

~~**Organ**~~	~~**Candidate is registered at a transplant hospital that is at or within the following this distance of the donor hospital**~~
~~Heart~~	~~250NM~~
~~Liver~~	~~150NM~~
~~Lung~~	~~250NM~~

~~If the multi-organ candidate is on a waiting list outside the geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.~~

When an OPO is offering a heart or lung, and a liver or kidney is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-4* must be offered the second organ.

Table 5-4 Second Organ for Heart or Lung PTRs

If the OPO is offering to PTRs appearing on the following match run:	And a PTR is also registered for one of the following organs:	The OPO must offer the second organ if the PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and meets the following criteria:
Heart	Liver or Kidney	Heart Adult Status 1, 2, 3 or pediatric 1A or 1B
Lung	Liver or Kidney	Lung allocation score of greater than 35

It is permissible for the OPO to offer the second organ to other multi-organ PTRs that do not meet the criteria above.

If the OPO is offering to PTRs appearing on either the heart or lung match runs, and two PTRs appear that both meet the criteria in *Table 5-4*, it is permissible for the OPO to offer the second organ to the PTR on the heart match run or the PTR on the lung match run, at the OPO's discretion.

8.7.C. Kidney Allocation in Multi-Organ Combinations

If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to Policy 8: Allocation of Kidneys:

- *Policy 5.10.E: Other Multi-Organ Combinations*
- *Policy 9.9: Liver-Kidney Allocation*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

8.7.~~C~~.D Multi-Organ Combinations Allocated but Not Transplanted

8.7.~~D~~.E Location of Donor Hospitals

9.9 Liver-Kidney Allocation

~~If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to Policy 8: Allocation of Kidneys:~~

- ~~*Policy 5.10.C: Other Multi-Organ Combinations*~~
- ~~*Policy 9.9: Liver-Kidney Allocation*~~
- ~~*Policy 11.4.A: Kidney-Pancreas Allocation Order*~~

If a host OPO is offering a kidney and a liver from the same deceased donor, then before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to candidates who meet eligibility according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation* and are one of the following:

1. Within 150 nautical miles of the donor hospital and have a MELD or PELD of 15 or higher
2. Within 250 nautical miles of the donor hospital and have a MELD or PELD of at least 29
3. Within 250 nautical miles of the donor hospital and status 1A or 1B.

The host OPO may then do either of the following:

1. Offer the kidney and liver to any candidates who meet eligibility in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*.
2. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.

OPTN

Public Comment Proposal

Calculate Median MELD at Transplant around Donor Hospital and Update Sorting within Liver Allocation

OPTN Liver and Intestinal Organ Transplantation Committee

Prepared by: Matthew Cafarella, MPH
UNOS Policy and Community Relations Department

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Calculate Median MELD at Transplant around Donor Hospital and Update Sorting within Liver Allocation

Affected Policies:	*Policy 1.2: Definitions* *Policy 9.4.A: MELD or PELD Score Exception Requests* *Policy 9.4.C.ii: Other MELD or PELD Score Exception Extensions* *Policy 9.4.D: Calculation of Median MELD or PELD at Transplant* *Policy 9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant* *Policy 9.5: Specific Standardized MELD or PELD Score Exceptions* *Policy 9.5.A: Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions* *Policy 9.5.B: Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions* *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions* *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions* *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions* *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions* *Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions* *Policy 9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions* *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions* *Policy 9.5.I.vii Extension of HCC Exceptions* *Policy 9.6.A: Waiting Time for Liver Candidates* *Policy 9.8: Liver Allocation, Classifications and Rankings* *Policy 9.8.D: Sorting Within Each Classification*
Affected Guidelines:	*National Liver Review Board Operational Guidelines*
Sponsoring Committee:	*Liver and Intestinal Organ Transplantation*
Public Comment Period:	*January 21, 2021 – March 23, 2021*

Executive Summary

On February 4, 2020, the use of donation service areas (DSAs) and OPTN Regions was removed from liver allocation with the implementation of the Acuity Circles (AC) allocation policy, which is a series of

concentric circles around the donor hospital.[1] When the AC policy was implemented, the geographic basis for the calculation of the median model for end-stage liver disease (MELD) at transplant (MMaT) was changed. The MMaT is used to assign MELD exception scores for liver transplant candidates whose medical urgency for transplant is not appropriately represented by their calculated MELD score. Under the AC policy, the MMaT score for each transplant program is based on a subset of transplants performed within 250 nautical miles (NM) of the transplant program. This calculation provides higher exception scores to candidates listed at transplant programs with a higher MMaT, where a higher MELD score is needed to access transplant. However, it also means that two exception candidates with the same exception diagnosis listed at different transplant programs, may receive different MELD exception scores. When two transplant programs with different MMaT scores are in close geographic proximity, MELD exception candidates listed at the two programs will be included on many of the same match runs with different MELD exception scores, despite having the same exception diagnosis and urgency for transplantation.

This proposal intends to increase equity by utilizing an MMaT calculated around each donor hospital instead of the transplant program to assign exception scores. Under this proposal, every donor hospital would have a calculated MMaT and all exception candidates on a match run based at a specific donor hospital would have an exception score relative to the MMaT for that donor hospital.

This update to the MMaT calculation necessitates a change to the order in which candidates are sorted within liver allocation classifications. Currently, within an allocation classification, liver candidates are sorted by MELD or pediatric end-stage liver disease (PELD) score, blood type compatibility, and then waiting time at score or higher. Under the proposed MMaT calculation, exception scores will fluctuate based on the location of the donor, so exception candidates are no longer able to be sorted based on time at score or higher. This proposal changes how liver candidates are sorted so that after MELD or PELD score and blood type compatibility, candidates with a calculated MELD or PELD will be ranked ahead of exception candidates. Subsequently, candidates with a calculated MELD or PELD score will be ranked by time at score or higher while exception candidates will be ranked by time since submission of earliest approved exception.

This proposal intends to improve equity in access to individual donor offers for exception candidates and better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation.

The OPTN Liver and Intestinal Organ Transplantation Committee is seeking public comment feedback on the proposed changes described above.

The Committee submits the following proposal for public comment under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs.”[2]

[1] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at https://optn.transplant.hrsa.gov/

[2] 42 CFR §121.4(a)

Background

When being listed for a liver transplant, candidates receive a calculated MELD or PELD score, which is based on a combination of the candidate's clinical lab values.[3] These scores are designed to reflect the probability of death on the waitlist within a 3-month period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned status 1A or 1B priority. When a transplant program believes that a candidate's calculated MELD or PELD score does not accurately reflect the candidate's medical urgency, they may request a score exception.

Under the National Liver Review Board (NLRB), which was implemented on May 14, 2019, most liver candidates with a MELD score exception are assigned a score relative to the MMaT for the area around the transplant program where they are listed.[4,5] Liver candidates with a PELD score exception are assigned a score relative to the median PELD at transplant (MPaT) for the nation. Prior to the NLRB, exception scores were not assigned relative to MMaT or MPaT. Instead, MELD or PELD exception candidates received a set score that increased with longer waiting time. The use of MMaT was designed to assign exception scores that appropriately rank exception candidates relative to other exception candidates and candidates with a calculated MELD score in the area where they are listed.

Before the AC policy, MMaT scores were calculated based on the DSA of the transplant program. All transplant programs within a DSA had the same MMaT. However, when the AC policy was implemented, which removed the use of DSAs and OPTN Regions from liver allocation policy, the geographic basis for the MMaT calculation was changed from the DSA to 250 NM around each candidate's transplant program.

When developing the AC policy, the Committee considered a number of options for replacing the use of DSA in the MMaT calculation, including a national MMaT and circles sizes of 150 NM, 250 NM, and 500 NM around each transplant program. The Committee ultimately decided that using a 250 NM circle around the transplant program was most appropriate because it would include a larger and more stable cohort than 150 NM, but was more reflective of MELD scores in the area around a transplant program than 500 NM. The Committee did not support a national MMaT because it fails to account for variation in MMaT across the nation.[6]

The Committee acknowledged that basing the MMaT calculation on the area around the transplant program, while basing allocation on the location of the donor hospital, would cause exception candidates on the same match run to have different exception scores.[7] However, the Committee felt that calculating MMaT based on the area around the transplant program would best approximate the pool of candidates with whom a candidate would compete for donor offers and the variation between

[3] The calculation for the MELD and PELD scores can be found in OPTN Policy, Available at https://optn.transplant.hrsa.gov/.
[4] *Proposal to Establish a National Liver Review Board,* OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at https://optn.transplant.hrsa.gov/
[5] Candidates with a MELD exception score of 40 and HCC candidates on their six month delay are not assigned an exception score relative to the MMaT.
[6] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at https://optn.transplant.hrsa.gov/
[7] Ibid.

transplant programs would even out over time.[8] Nonetheless, transplant programs in close geographic proximity have similar access to the same donor hospitals and if one transplant program has a higher MMaT, exception candidates at that program will be ranked higher than exception candidates at the nearby transplant program on many match runs.

For example, under the current system, transplant programs in Chicago, IL have an MMaT of 27. The transplant programs in Milwaukee, WI, which is 70 NM from Chicago, IL, have an MMaT of 28.[9] The higher MMaT in Milwaukee reflects the fact that a higher MELD score is typically needed to access transplantation in that area. However, for matches run at donor hospitals in close proximity to both Milwaukee and Chicago, the exception candidates listed in Chicago will be ranked lower than the exception candidates listed in Milwaukee, despite having the same exception diagnosis. Because most exception candidates are provided a score of MMaT-3, they typically appear on match runs together, essentially creating a block of exception candidates at a certain MELD or PELD score. This situation exists wherever there are two transplant programs with different MMaT scores in close geographic proximity.

Despite the fact that transplant programs in close geographic proximity can have different MMaT scores, causing exception candidates to appear on many of the same match runs with different exception scores, every transplant program has access to different donor hospitals. For example, organ offers for matches run at a donor hospital in Indianapolis will typically be offered to candidates listed at transplant programs in Chicago, which is within 150 NM of Indianapolis, before being offered to candidates listed at transplant programs in Milwaukee, which is more than 150 NM from Indianapolis. Therefore, it is important to note that while candidates at the programs in Milwaukee and Chicago appear within the same allocation classification for many donor hospitals due to their close proximity, there are donor hospitals where candidates in Chicago appear higher on the match run.

To address the fact that exception candidates at transplant programs within close geographic proximity can have different assigned exception scores, the Committee is proposing a change to the MMaT calculation to instead be based on the area around the donor hospital and all exception candidates would be assigned an exception score relative to the MMaT of the donor hospital where the match is run. The Committee is proposing this change based on member feedback after implementation of the AC policy that highlighted the situation described above and advocated for the concept of calculating the MMaT based on the donor hospital. The Committee reviewed and considered this feedback in the development of this proposal.

Under the proposed MMaT calculation, candidates' exception scores will not be known prior to the match being executed because the scores will be based on the MMaT of the donor hospital where the match is being run. Therefore, candidates with a MELD exception will not be able to be sorted based on time at current score or higher score and the proposal also includes changes to how candidates are sorted within allocation classifications.

Purpose

The purpose of this proposal is to increase equity in access to individual donor offers for MELD exception candidates listed at different transplant programs and better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation.

[8] Ibid.

[9] These MMaT scores are current as of the drafting of this document on December 10, 2020.

The Committee puts forth this proposal to address the situation described above based on initial experience with the NLRB and AC policy. The Committee reviewed and discussed post-AC implementation data and noted that the data represented just a small time period and was impacted by the COVID-19 pandemic. Despite a lack of quantitative analysis showing a disparity, the Committee determined that the situation described above warrants a change and the proposal increases equity in access to specific donor offers.[10]

The Committee submits the following proposal for public comment under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[11]

Overview of Proposal

The proposal alters a number of components of liver allocation. The subsequent sections provide further detail on the proposed changes.

Median MELD at Transplant around the Donor Hospital

The Committee is proposing to change the MMaT calculation to be based around the donor hospital as opposed to the transplant program. While this is a significant change in the MMaT calculation, many of the underlying principles in the MMaT calculation are remaining the same.

The MMaT for each transplant program is calculated by using the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 NM of the candidate's listing hospital in a 365 day period, excluding recipients who were transplanted with livers from living donors, donation after circulatory death (DCD) livers, or livers from donors at donor hospitals more than 500 NM away from the transplant hospital. Candidates who were status 1A or 1B at the time of transplant are excluded from the calculation as well. The MPaT is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation. The MPaT calculation also excludes recipients who were transplanted with livers from living donors, donation after circulatory death (DCD) livers, livers from donors at donor hospitals more than 500 NM away from the transplant hospital and candidates who were status 1A or 1B at the time of transplant. The MMaT and MPaT are both updated twice a year.

The Committee discussed the following decision points in developing the proposal.

Initial Circle Size

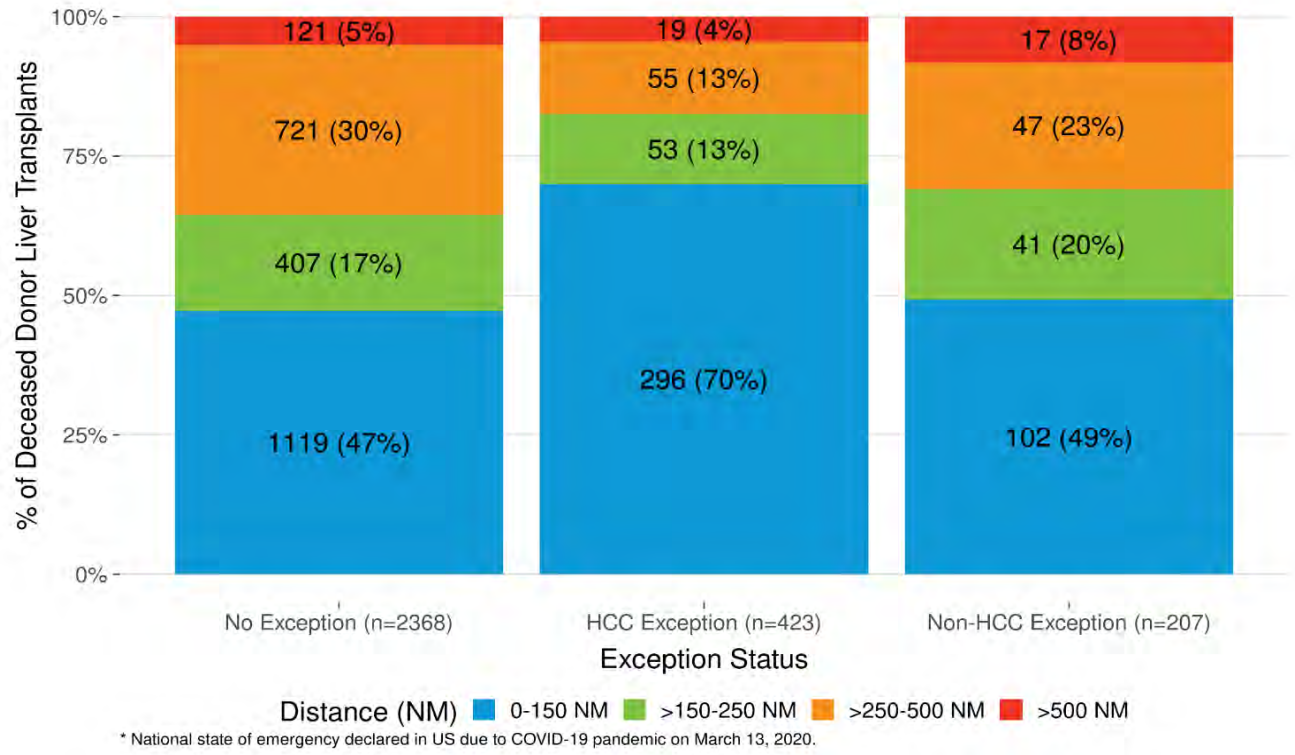
The first question the Committee considered in developing MMaT around the donor hospital was what initial circle size should be used in the calculation. They considered 150 NM, 250 NM, and 500 NM

[10] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at https://optn.transplant.hrsa.gov/
[11] 42 CFR §121.4(a)

options and ultimately determined that utilizing a 150 NM circle around the donor hospital best reflects the MELD score needed to access transplant in the area around the donor hospital.[12]

Figure 1 shows that, since the implementation of the AC policy, the majority of exception candidates have been transplanted with organs from donors within 150 NM of the donor hospital. For candidates with an HCC exception, the proportion of transplants that were performed within 150 NM of the donor hospital is even higher (70%), while for non-HCC exceptions, it is 49%. Based on this information, the Committee agreed that it was most important to accurately calculate the MMaT for the 150 NM area around the donor hospital in order to reflect proximate access to transplant and appropriately rank exception candidates and candidates with a calculated MELD score within the 150 NM circle.

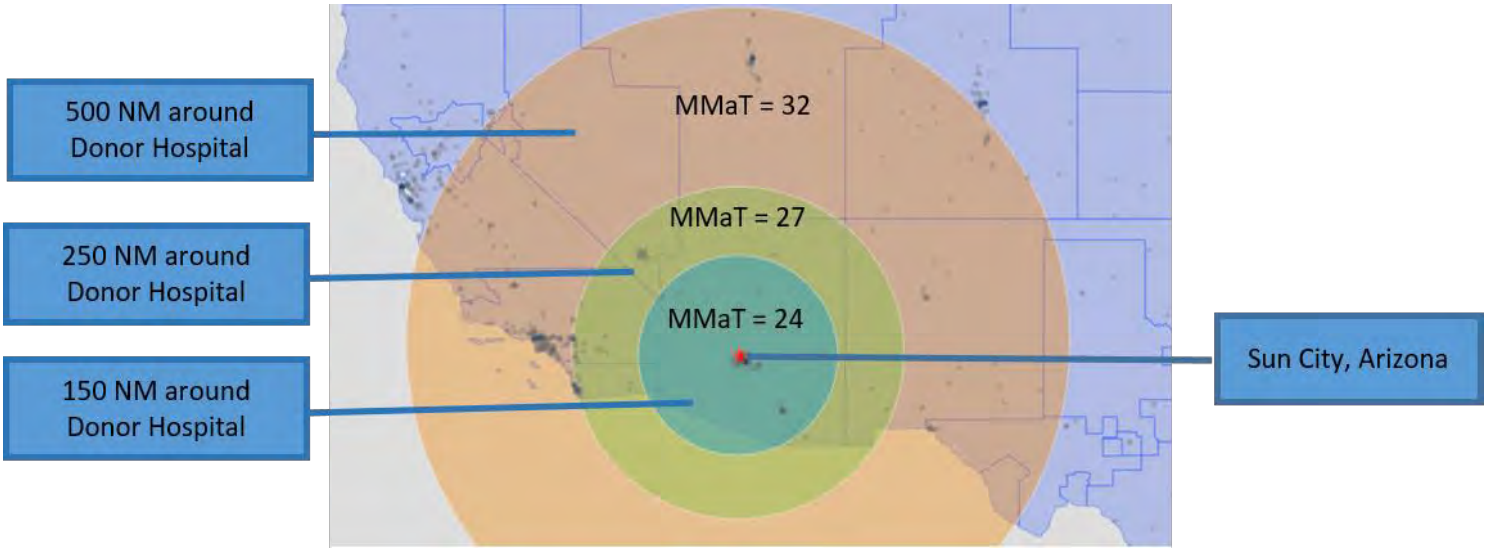
Figure 1: Deceased Donor, Liver-Alone Transplants by Exception Status and Distance from Donor Hospital to Transplant Program, during 2/4/2020-8/4/2020



To highlight the Committee's decision, **Figure 2** below depicts an example of the proposed approach for a donor based in Sun City, Arizona.

[12] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at https://optn.transplant.hrsa.gov/

Figure 2: Donor Example in Sun City, Arizona



In this sample scenario, the MMaT within 150 NM around the donor hospital is 24, within 250 NM, it is 27, and within 500 NM, it is 32. For reference, the current MMaT for the transplant programs in Phoenix, AZ is 23. The MMaT for the transplant programs in Phoenix, AZ is instructive as it shows the MELD score that a candidate typically needs in order to be transplanted in the area.

If the MMaT around the donor hospital utilized a 250 NM circle, exception candidates on a match run for a donor in Sun City, AZ would be provided exception scores relative to an MMaT of 27. The Committee felt that utilizing a 250 NM circle would inappropriately rank exception candidates relative to candidates with a calculated MELD or PELD score in the 150 NM area around the donor hospital, which is the first geographic unit of allocation used for candidates with a MELD score.[13] If exception candidates were provided an exception score relative to an MMaT of 27, they would be ranked relatively highly compared to the candidates with a calculated MELD registered at transplant programs in the area around the donor hospital, where the MMaT is 23. The Committee felt it was most important to align the MMaT calculation with the initial geographic unit of allocation because this is where most exception candidates are transplanted.[14] The Committee used the same rationale to rule out the use of a 500 NM circle.

The Committee did note that utilizing either a 250 NM circle or 500 NM would have some benefits. Primarily, a 250 NM circle would attenuate some of the differences between high MELD and low MELD areas that are in close proximity. This is also seen in the Sun City, AZ example. As noted above, using a 150 NM circle around the donor in Sun City, AZ means that all exception candidates on the match run are provided an exception score relative to 24. This works well for the transplant programs in Phoenix, AZ, but exception candidates in San Diego, CA are ranked relatively lowly compared to candidates with a calculated MELD or PELD in that area, where the MMaT is 32. If a 250 NM circle were utilized, the MMaT would be 27, which is less aligned with the MMaT in the area immediately around Sun City, AZ but more

[13] Candidates listed as status 1A or 1B within 500 NM of a donor hospital are offered the liver before any MELD or PELD candidates within 150 NM.
[14] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at https://optn.transplant.hrsa.gov/

aligned with the MMaT in southern California. Utilizing a 250 NM circle may attenuate some of the differences in MMaT between areas. However, it is more likely that the liver is accepted for an exception candidate within 150 NM of the donor hospital, than 250 NM.

The Committee also noted that both a 250 NM and 500 NM circle would reduce variability in MMaT scores across the nation. However, the Committee remained in agreement that it was more important to ensure MMaT reflected the MELD score needed to appropriately access transplant within 150 NM of the donor hospital, as this is the first geographic unit used in allocation for MELD candidates and post-AC data shows that the majority of exception candidates are transplanted with livers from donor hospitals within 150 NM of the transplant program. [15]

The Committee is seeking public comment feedback on if a 150 NM circle should be used to calculate the MMaT for donor hospitals or if a different circle size should be utilized.

MMaT Calculation Cohort Size

The Committee then considered what minimum cohort size of previous transplants should be required to calculate the MMaT for each donor hospital and how to ensure that such a cohort is available for all donor hospitals. The Committee is proposing that the minimum cohort needed to calculate an MMaT should be two transplant programs and ten qualifying transplants.[16] If there are not at least two transplant programs and ten qualifying transplants within 150 NM of a donor hospital, the geographic area used to calculate MMaT will increase in 50 NM increments until the minimum cohort threshold is met.

In current policy, there must be at least ten transplants within 250 NM in a prior 365 day period to calculate MMaT for a transplant program. When discussing the minimum cohort size needed to calculate the MMaT for each donor hospital, the Committee agreed that there was no reason to deviate from the ten transplant minimum. This number ensures that there is a sufficiently large cohort of recent transplants to calculate MMaT. However, the Committee also determined that it is important to ensure that the MMaT for a particular donor hospital is not based on transplants performed at only one transplant program. Therefore, in addition to the ten transplant minimum, the Committee is proposing that there must also be at least two transplant programs included in the MMaT calculation for each donor hospital. This will ensure that the transplant behavior of a single transplant program does not dictate the MMaT for a donor hospital, and therefore determine the exception scores for all MELD exception candidates on that match run. The Committee intends to continue to utilize a prior 365 day cohort in the MMaT calculation.

The Committee is also proposing that if a transplant program has not performed a transplant that is included in the MMaT calculation, the program is not counted in the two program threshold. This ensures that a transplant program that has only performed pediatric transplants or living donor transplants, and therefore is not contributing to the MMaT calculation, is not included in the cohort threshold. If such a program were included, there is the possibility that the MMaT for a donor hospital would be based on transplants performed at only one transplant program.[17]

[15] Ibid.
[16] Qualifying transplants is defined as those transplants included in the MMaT calculation. Additional details are provided in subsequent sections of the proposal.
[17] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at https://optn.transplant.hrsa.gov/

The Committee is seeking public comment feedback on the minimum number of transplant programs and minimum number of transplants needed to calculate MMaT, as well as the use of only transplant programs that have performed a qualifying transplant.

When discussing the minimum cohort size needed to calculate the MMaT for each donor hospital, the Committee was aware that not every donor hospital would have two transplant programs and ten transplants performed within 150 NM. Under the current MMaT calculation, if there have not been ten transplants within 250 NM of a transplant program, the cohort timeframe is extended back to be based on 730 days. This works because the MMaT calculation for a transplant program can be based on the transplants performed at that program. However, there are donor hospitals where there simply are no transplant programs within 150 NM. As such, extending the cohort back in time would serve no purpose.

To address this, the Committee is proposing that when the minimum cohort is not met within 150 NM around a donor hospital, the geographic basis for the calculation increases in 50 NM increments until the minimum cohort size is satisfied. Increasing the circle size in 50 NM increments ensures that the minimum cohort size is met, while not expanding the geographic basis for the MMaT calculation beyond what is necessary.

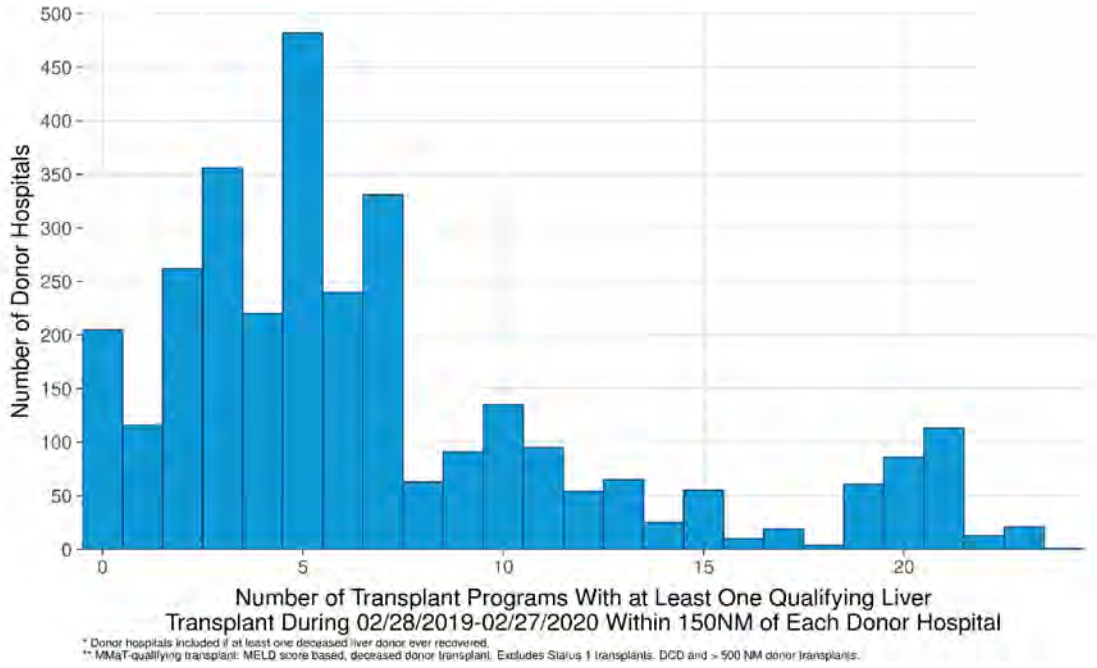
When initially discussing how to handle donor hospitals without two transplant programs and ten transplants within 150 NM, the Committee considered increasing the circle size to align with the geographic units used in the allocation sequences (150 NM, 250 NM, 500 NM, and national). However, the Committee noted that aligning the MMaT calculation circles with the allocation circles was not necessary and that increasing in 50 NM increments created a more appropriate approach. By increasing in smaller increments, the MMaT for the donor hospital is more likely to reflect access to transplant in the area closer to the donor hospital, which is the Committee's intent.

The Committee is seeking public comment feedback on the plan to increase the geographic basis used to calculate MMaT by 50 NM increments when the minimum cohort size is not met.

The Committee reviewed data on the number of liver transplant programs within 150 NM of each donor hospital with at least one MMaT-qualifying transplant. As seen in **Figure 3**, only 318 donor hospitals out of 3,213 had less than two transplant programs within 150 NM. This means that for 90% of donor hospitals, MMaT will be calculated based on a 150 NM circle, assuming that there have been at least ten transplants. The Committee considered this data when determining the minimum cohort size, as it would be impractical to choose an initial circle sire that was rarely large enough to meet the minimum cohort threshold.[18]

[18] Ibid.

Figure 3: Number of Liver Transplant Programs within 150 NM of Each Donor Hospital with at Least One MMaT-Qualifying Transplant during 2/28/2019-2/27/2020



MMaT Exclusions, Update Schedule, and Cohort Timeframe

In the current calculation for MMaT, recipients who are transplanted with livers from living donors, DCD donors, and donors at donor hospitals more than 500 NM from the recipient's transplant program are excluded. The calculation also does not include recipients who were listed as status 1A or 1B at the time of transplant. Living donor recipients do not typically receive transplants based their MELD score, and are often recipients of directed donation. Livers from DCD donors and from donors more than 500 NM from the recipient's transplant program tend to be transplanted into candidates lower on the match run with lower MELD scores. These transplants are considered to be more aggressive transplants. The Committee agreed that the same exclusions should remain for the MMaT around the donor hospital, as including these transplants may disincentivize the use of these organs.

In addition, the current MMaT calculation is updated twice a year based on a cohort from a prior 365 day period. The Committee felt that the same timeframe and update schedule were appropriate, as these two aspects of the current MMaT calculation work well and there is no reason to change either aspect of policy.

The Committee is seeking public comment feedback on the MMaT calculation exclusions, update schedule and cohort timeframe.

Donor Hospitals in Hawaii, Puerto Rico, and Alaska

The Committee is proposing that donor hospitals in Hawaii and Puerto Rico do not need to meet the two transplant program threshold due to their geographic isolation. The Committee discussed if donor hospitals in Alaska warranted unique consideration and determined that no additional changes were needed. While all three locations are geographically isolated from the contiguous U.S., there are liver

transplant programs located in both Hawaii and Puerto Rico. There is currently no liver transplant program located in Alaska.

In the AC policy, livers from non-DCD donors who are between ages 18 and 69 are allocated to all candidates with a MELD or PELD of 15 or higher within 500 NM of the donor hospital before being offered to more urgent candidates across the nation. In Hawaii and Puerto Rico, this means that livers from donors at donor hospitals on the two islands are offered to all candidates with a MELD or PELD down to 15 on each respective island before being offered to any candidates in the contiguous U.S. Because of this, the Committee agreed that it was appropriate to take additional measures to ensure that the MMaT for donor hospitals on the islands accurately represented the MELD score needed to access transplant on each respective island. This is complicated, however, by the two transplant program minimum cohort threshold. For donor hospitals in Hawaii, if two transplant programs were required to be included in the MMaT calculation, the calculation would include the transplant program in Hawaii and the closest transplant program in the contiguous U.S., which is in San Francisco, CA. In Puerto Rico, the MMaT calculation would include the transplant program in Puerto Rico and the closest transplant program in Miami, FL.

The inclusion of transplants performed at transplant programs in San Francisco, CA and Miami, FL would increase the MMaT at donor hospitals in Hawaii and Puerto Rico respectively such that exception candidates listed on match runs for donors in Hawaii and Puerto Rico would be inappropriately advantaged relative to candidates with a calculated MELD or PELD score.[19] This difference is particularly important in Hawaii and Puerto Rico because, as previously mentioned, most donors on the two islands are offered to most candidates on the respective islands before being offered more broadly.

As a result, the proposal includes a provision that does not require the donor hospitals in Puerto Rico or Hawaii to meet the two transplant program minimum threshold. The MMaT for donor hospitals in Hawaii and Puerto Rico must include at least ten transplants in a prior 365 day period. If there are not ten qualifying transplants, in the previous 365 days, the time period will be extended to a total of 730 days. In addition, there are donor hospitals in Hawaii that are more than 150 NM from the transplant program on the island. As a result, the initial circle size used to calculate MMaT for donor hospitals in Hawaii and Puerto Rico is 250 NM. This ensures that donor hospitals in Hawaii and Puerto Rico have MMaT scores that still include a sufficiently large cohort of transplants but remain reflective of access to transplant on the islands and that exception candidates are appropriately ranked relative to candidates with a calculated MELD or PELD score.

The Committee discussed whether Alaska required similar consideration. Under the AC policy, donors that become available in Alaska are considered to be located at the Seattle-Tacoma Airport (Sea-Tac) for purposes of allocation. This is because there is no liver transplant program in Alaska and all donors are routed through Sea-Tac. The Committee wanted to ensure that the MMaT calculation reflected the MMaT in the Seattle, WA area. However, because the Committee decided to increase the geographic area used to calculate MMaT in 50 NM increments, for donor hospitals in Alaska, the circle will get progressively larger until it reaches Seattle. Therefore, no special consideration is needed for donor hospitals in Alaska.

[19] As of the drafting of this document, the MMaT for the transplant program in Hawaii is 22. In San Francisco, the MMaT is 30. The MMaT for the transplant program in Puerto Rico is 18. In Miami, the MMaT is 26.

The Committee is seeking public comment feedback on the proposal to calculate MMaT at donor hospitals in Hawaii and Puerto Rico. The Committee is also seeking public comment feedback on the proposal to calculate MMaT for donor hospitals in Alaska.

Median PELD at Transplant

In current policy, the MPaT is calculated based on the median of the PELD scores of liver recipients who were less than 12 years old at the time of transplant across the nation.[20] MPaT is calculated using a national cohort because there a fewer PELD transplants performed and these recipients are typically transplanted at higher PELD scores.[21] Because MPaT is calculated using a national cohort and all PELD exceptions are assigned relative to the national MPaT, there is no disparity between PELD exception candidates, similar to what exists for MELD exception candidates. Therefore, the proposal does not change how MPaT is calculated.

The Committee is seeking public comment feedback on if there should be any corresponding changes to the MPaT calculation.

Sorting within Liver Allocation

Within each allocation classification, liver candidates are sorted in the following order:

1. MELD or PELD score
2. Blood type compatibility (identical, compatible, then incompatible)
3. Waiting time at the current or higher MELD or PELD score (highest to lowest)
4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
5. Total waiting time (highest to lowest)

This means that when ranking candidates within an allocation classification, candidates with the highest MELD or PELD score in that classification appear first on the match run. Within the same MELD or PELD score, candidates are then ranked based on blood type compatibilty, with blood type identical candidates being ranked ahead of blood type compatible candidates, who are ranked ahead of blood type incompatible candidates. Within the same blood type compatibility, candidates are then ranked based on time at current MELD or PELD score or higher MELD or PELD score. If multiple candidates of the same MELD or PELD score have the same blood type compatibility and time at score or higher, they are then ranked by time since submission of initial approved exception. And if all else is equal, the candidates are then sorted by total waiting time.

The use of MMaT around the donor hospital requires that the way in which candidates are sorted within allocation classifications be changed. By using MMaT around the donor hospital, MELD exception scores for exception candidates will fluctuate based on the MMaT of the donor hospital and will only be known once the match is run. If one donor hospital has an MMaT of 30, most MELD exception candidates on that match run will have an exception score of 27. However, the same exception candidate could be on a match run based at a donor hospital where the MMaT is 27 on the same day, and therefore have an

[20] The MPaT calculation also excludes status 1A/1B recipients and recipients who are transplanted with livers from living donors, DCD donors, and donors at donor hospitals more than 500 NM from the recipient's transplant program.
[21] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at https://optn.transplant.hrsa.gov/

exception score of 24. MELD exception candidates will no longer have a constant MELD exception score and their specific score will only be known for a match run once the match is executed. Due to the variability in MELD exception scores based on the MMaT of the donor hospital, it is impossible to capture time at current score or higher score for MELD exception candidates.

To address this issue, the Committee is proposing that MELD or PELD exception candidates be ranked by time since submission of earliest approved MELD or PELD exception request while candidates with a calculated MELD or PELD score be ranked by time at current calculated MELD or PELD score or higher calcualted MELD or PELD score. Further, the Committee is proposing that within the same MELD or PELD score and blood type compatibility, candidates with a calculated MELD or PELD score be ranked ahead of candidates with a MELD or PELD exception score.

In developing the proposal, the Committee first determined that exception candidates with the same MELD or PELD score and blood type compatibility should be ranked relative to each other based on time since submission of earliest approved exception. This sorting method already exists in policy and ranks exception candidates who have had an exception for a longer period of time ahead of exception candidates who have had an exception for a shorter period of time, when MELD or PELD is equal and blood type compatibility is the same. Similarly, the Committee agreed that candidates with a calculated MELD or PELD score should be ranked by time at current calculated score or higher calculated score, as this sorting method already exists in policy and it is appropriate to rank calculated MELD or PELD candidates based on time at score or higher, when MELD or PELD score and blood type compatibility are equal.

The Committee reviewed sample scenarios where exception candidates were sorted based on time since submission of earliest approved exception and calculated MELD or PELD candidates were sorted based on time at current calculated score or higher, without any further distinction between exception and calculated MELD or PELD candidates. In these scenarios, the Committee realized that the two proposed methods for counting waiting time disproportionately advantaged exception candidates.

In most cases, exception requests are submitted for exception candidates around the time they are registered and active on the waitlist, meaning that the use of time since submission of earliest approved exception was, more or less, giving exception candidates waiting time since they were added to the waitlist. However, for most calculated MELD or PELD candidates, their time at calculated score or higher was dictated by the laboratory update schedule. In the standard candidate trajectory, where a candidate's MELD or PELD score increases the longer he or she is on the waitlist, candidates were typically only receiving time since the last time their laboratory values were updated.[22] Therefore, in most of the sample scenarios, exception candidates were being ranked ahead of candidates with a calculated MELD or PELD score when the candidates had the same MELD or PELD score and blood type compatibility.

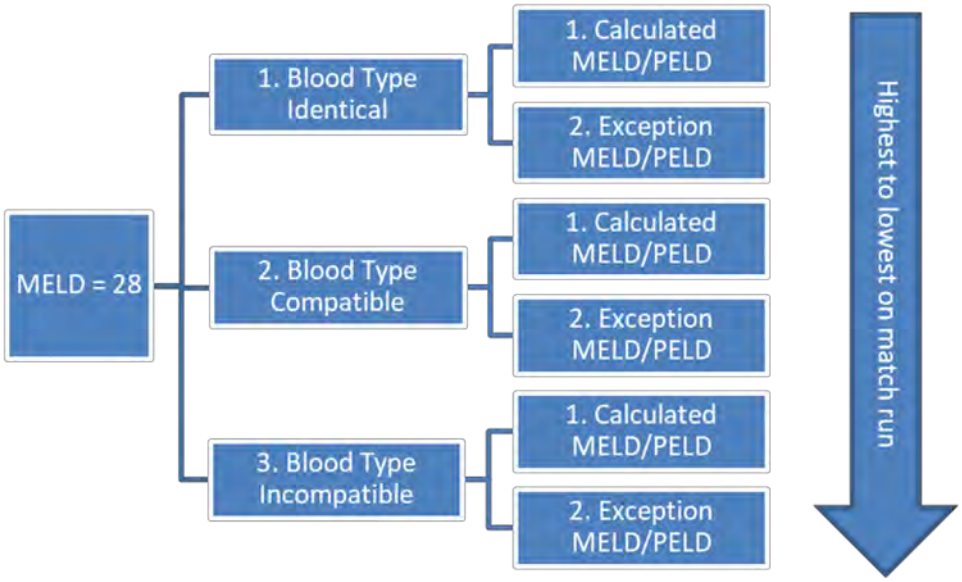
To address this concern, the Committee is proposing the addition of a new level of sorting after blood type compatibility that ranks candidates with a calculated MELD or PELD score ahead of candidates with a MELD or PELD exception score. It is important to reiterate that candidates with a calculated MELD or PELD score will be ranked ahead of exception candidates only when MELD or PELD score and blood type compatibility are the same. An exception candidate with a higher MELD or PELD will still be ranked above a calculated MELD or PELD candidate with a lower score. **Figure 4** below depicts the proposed

[22] The laboratory update schedule is described in OPTN Policy which is available at https://optn.transplant.hrsa.gov/

sorting algorithm beginning with a MELD or PELD score of 28. As a reminder, within each allocation classification, liver candidates are sorted in the following order:

1. MELD or PELD score
2. Blood type compatibility (identical, compatible, then incompatible)
3. Waiting time at the current or higher MELD or PELD score (highest to lowest)
4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
5. Total waiting time (highest to lowest)

Figure 4: Sorting within Allocation Classifications



Ranking calculated MELD or PELD candidates ahead of exception MELD or PELD candidates of the same MELD or PELD score and blood type compatibility is based on the clinical experience of the Committee and the published literature, which shows that candidates with a MELD or PELD exception score have historically had better waitlist outcomes than candidates with a calculated MELD or PELD score.

Previously published literature has shown that candidates with a MELD or PELD exception, specifically those candidates with an exception for HCC, experienced better waitlist outcomes compared to non-HCC candidates, including: lower waitlist dropout rates at 12 months (11.5% for HCC candidates compared to 17.7% for non-HCC candidates) and higher likelihood of transplant at 90 days and lower likelihood of death at 90 days than non-HCC candidates with the same calculated MELD score as the HCC exception score.[23,24] Additional research showed that the risk of waitlist removal for HCC candidates remained stable at increasing MELD scores and was significantly lower than non-HCC candidates at similar MELD scores.[25] Overall, previous research has consistently shown that candidates with an HCC

[23] K. Washburn et al., "Hepatocellular Carcinoma Patients Are Advantaged in the Current Liver Transplant Allocation System," *American Journal of Transplantation* 10, no. 7 (May 10, 2010): 1643–48, https://doi.org/10.1111/j.1600-6143.2010.03127.x.

[24] A. B. Massie et al., "MELD Exceptions and Rates of Waiting List Outcomes," *American Journal of Transplantation* 11, no. 11 (September 15, 2011): 2362–71, https://doi.org/10.1111/j.1600-6143.2011.03735.x.

[25] David Goldberg et al., "Increasing Disparity in Waitlist Mortality Rates with Increased Model for End-Stage Liver Disease Scores for Candidates with Hepatocellular Carcinoma versus Candidates without Hepatocellular Carcinoma," *Liver Transplantation* 18, no. 4 (March 29, 2012): 434–43, https://doi.org/10.1002/lt.23394.

exception have lower mean days on the waiting list, higher transplantation rates, and lower waiting list death rates.[26]

These analyses predate a number of liver allocation policy changes that were designed to equalize waitlist outcomes between HCC and non-HCC candidates. First, in 2015, the HCC "cap and delay" policy was implemented, which instituted a six-month delay in MELD exception score assignment for HCC candidates and capped HCC exception scores at 34.[27,28] Published research suggests that these policy changes did increase equity between HCC and non-HCC candidates, with some advantage for HCC candidates remaining.[29] It is also necessary to note that this research is primarily restricted to HCC exceptions, which accounted for 76% of all exception request forms in the first six months of AC, but there are other diagnoses for which candidates receive exceptions.[30]

Also, the NLRB and AC policies significantly changed how exceptions scores are assigned and how exception candidates are prioritized. There has been no quantitative analysis conducted after implementation of these two policies that show the impact on HCC and non-HCC waitlist outcomes due to the lack of appropriate follow-up time.

The Committee also cited their medical judgement to support the ranking of candidates with a calculated MELD or PELD score ahead of exception candidates of the same MELD or PELD score and blood type compatibility. In their medical experience, the Committee agreed that, on average, a candidate with a calculated MELD or PELD is more medically urgent than a candidate that has a MELD or PELD score exception.[31]

The Committee considered a proposal to weight waiting time differently for exception and calculated MELD or PELD candidates that would provide priority for candidates with a calculated MELD or PELD but still included a pathway for exception candidates to gain priority with longer waiting time. The Committee felt that this would be too complicated and it would be difficult to determine the proper weighting coefficient.[32]

The Committee is seeking public comment feedback on the proposed sorting approach, specifically on the ranking of candidates with a calculated MELD or PELD score ahead of exception candidates of the same MELD or PELD score and blood type compatibility.

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[26] Patrick Grant Northup et al., "Excess Mortality on the Liver Transplant Waiting List: Unintended Policy Consequences and Model for End-Stage Liver Disease (MELD) Inflation," *Hepatology* 61, no. 1 (October 29, 2014): 285–91, https://doi.org/10.1002/hep.27283.

[27] *Proposal to Delay HCC Exception Score Assignment,* OPTN Liver and Intestinal Organ Transplantation Committee, November 2014

[28] *Proposal to Cap the HCC Exception Score at 34,* OPTN Liver and Intestinal Organ Transplantation Committee, November 2014

[29] Tanveen Ishaque et al., "Liver Transplantation and Waitlist Mortality for HCC and Non-HCC Candidates Following the 2015 HCC Exception Policy Change," *American Journal of Transplantation* 19, no. 2 (November 9, 2018): 564–72, https://doi.org/10.1111/ajt.15144.

[30] OPTN Descriptive Data Request. "Out-of-the-Gate Monitoring of Liver and Intestine Acuity Circles Allocation, 6 Month Report Removal of DSA and Region as Units of Allocation" Prepared for the OPTN Liver and Intestinal Organ Transplantation Committee, October 22, 2020

[31] See Acuity Circles Subcommittee meeting summary, August 12, 2020. Available at https://optn.transplant.hrsa.gov/

[32] See Acuity Circles Subcommittee meeting summary, August 26, 2020. Available at https://optn.transplant.hrsa.gov/

Additional Changes

The Committee is seeking feedback on a number of additional changes that are part of the proposal.

Approved vs. Assigned

In current policy, if the NLRB fails to make a decision on an initial exception or exception extension request within 21 days of the day of submission, the candidate is assigned the requested score. There is no clear distinction in OPTN policy between exception requests that are reviewed and *approved* by the NLRB and those requests where the NLRB failed to make a decision and the candidate is *assigned* the requested score.

Included in this proposal are a number of clarifications to make policy more consistent in the distinction between approved and assigned exceptions.

The primary change to note as part of these clarifications relates to HCC exceptions. Currently, candidates with an approved or assigned HCC exception can be automatically approved for an HCC extension, even if the initial exception request is not automatically approved, as long as the candidate meets standardized extension criteria. The current policy states that only candidates with an approved exception can receive these automatic extensions. However, HCC candidates with an assigned exception are eligible to have extensions automatically approved because the distinction between approved and assigned exceptions has not previously been made. The Committee's concern is that candidates with an assigned exception will have subsequent extensions automatically approved and the case will never be appropriately reviewed. By distinguishing between approved and assigned exceptions throughout policy, only HCC candidates with an approved exception will be able to have subsequent extensions automatically approved, which is the Committee's intent.[33]

The Committee is seeking public comment feedback on the distinction between approved versus assigned exceptions in policy.

Minimum Exception Score

In developing the MMaT around the donor hospital proposal, the Committee recognized that there is the possibility for a donor hospital to have an MMaT score below 18. This is significant because livers from non-DCD donors between the ages 18 and 69 are allocated to candidates down to MELD or PELD 15 in the area around the donor hospital before being offered to more medically urgent candidates across the nation. If a donor hospital were to have an MMaT score equal to 17, most MELD exception candidates on the match run would have an exception score equal to MELD 14, meaning that the liver would be offered to all candidates with a MELD or PELD score of 15 or higher across the nation before being offered to a MELD exception candidate located in closer geographic proximity to the donor hospital.

This is not a new concern, as current policy includes a minimum exception score of 15 for candidates with a standardized exception. However, the concern is compounded by the fact that transplant programs will not be aware of the MMaT score at every donor hospital, so they cannot alter scores

[33] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 6, 2020. Available at https://optn.transplant.hrsa.gov/

based on a specific MMaT. Therefore, the Committee is proposing to extend the minimum exception score of 15 to include all MELD or PELD exceptions, both standardized and non-standardized.

This requires a change to the current policy for exception candidates on the six-month HCC delay. Currently, HCC candidates on their initial exception or first extension are provided an exception score of six, which is lower than proposed minimum score of 15. Under the proposed policy, transplant programs will still apply for exceptions for these candidates but instead of receiving a score of six, they will appear on match runs with their calculated MELD score. For HCC candidates that do not meet standardized criteria, transplant programs will be able to request an exception that correlates to the six month delay. For both standardized and non-standardized HCC exceptions, the candidates will have exceptions and will be accruing time since earliest approved exception request.

The Committee is seeking public comment feedback on the minimum exception score and if there is any reason to request a score lower than 15.

Requesting an Adjustment, not a Specific Score

Currently, transplant programs request a specific score for MELD or PELD exception candidates. For example, if the MMaT at a transplant program is 30, the program would submit a request for MELD 27 to align with MMaT-3.

With this proposal, MMaT will fluctuate based on the MMaT of the donor hospital. Transplant programs will no longer be able to request a specific exception score, as MMaT and, consequently exception scores, will change with each donor hospital. As a result, transplant programs will need to request an adjustment of a certain amount of points higher or lower than MMaT or MPaT, instead of specific scores. This change in the system will impact PELD exception requests, even though the MPaT calculation is not changing.

The Committee noted that transplant programs should still be able to specifically request exceptions for MELD or PELD 40 and above as these candidates are particularly urgent and a transplant program would only request such a high score of a specific purpose. As a result, in the proposal, transplant programs will be able to request a specific score if the score is for MELD 40 or PELD 40 and higher. These exception scores are not tied to MMaT or MPaT and will not change based on the donor hospital or an updated MPaT.

The Committee is seeking public feedback on requesting score adjustments as opposed to specific scores and if that change will be feasible for transplant programs.

New Donor Hospitals

In 2019, there was an average of 3.5 new donor hospitals added to UNet^{SM} each month. This does not include adjustments to the exact location of donor hospitals already in the system. For both new donor hospitals and updates to the location of an already-existing donor hospital, UNet will have the ability to automatically calculate an MMaT prior to the initiation of any liver match run. The MMaT for existing donor hospitals will still be updated twice each year as outlined in policy. The cohort used for new donor hospitals will align with the most recent bi-annual update to all MMaT scores.

NOTA and Final Rule Analysis

The Committee submits the proposed changes to liver allocation policy for Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[34] The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment[35]** because it is an evidenced-based change relying on the following evidence:
    - Published literature showing that candidates with a calculated MELD or PELD score have historically worse waitlist outcomes than candidates with a MELD or PELD exception. Specifically, previously published literature has shown that candidates with an HCC exception have lower waitlist dropout rates at 12 months (11.5% for HCC candidates compared to 17.7% for non-HCC candidates) and higher likelihood of transplant at 90 days and lower likelihood of death at 90 days than non-HCC candidates with the same calculated MELD score as the HCC exception score.[36,37] Additional research has shown that the risk of waitlist removal for HCC candidates remained stable at increasing MELD scores and was significantly lower than non-HCC candidates at similar MELD scores.[38]
    - The Committee also cited their medical judgement that, on average, a candidate with a calculated MELD or PELD is more medically urgent than a candidate that has a MELD or PELD score exception.[39]
- **Seeks to achieve the best use of donated organs[40] by** ensuring organs are allocated and transplanted according to medical urgency.
    - This proposal seeks to achieve the best use of donated organs by ensuring that liver transplant candidates with a MELD or PELD exception are appropriately ranked relative to other exception candidates and candidates with a calculated MELD or PELD score.

[34] 42 CFR §121.4(a).
[35] 42 CFR §121.8(a)(1).
[36] K. Washburn et al., "Hepatocellular Carcinoma Patients Are Advantaged in the Current Liver Transplant Allocation System," *American Journal of Transplantation* 10, no. 7 (May 10, 2010): 1643–48, https://doi.org/10.1111/j.1600-6143.2010.03127.x.
[37] A. B. Massie et al., "MELD Exceptions and Rates of Waiting List Outcomes," *American Journal of Transplantation* 11, no. 11 (September 15, 2011): 2362–71, https://doi.org/10.1111/j.1600-6143.2011.03735.x.
[38] David Goldberg et al., "Increasing Disparity in Waitlist Mortality Rates with Increased Model for End-Stage Liver Disease Scores for Candidates with Hepatocellular Carcinoma versus Candidates without Hepatocellular Carcinoma," *Liver Transplantation* 18, no. 4 (March 29, 2012): 434–43, https://doi.org/10.1002/lt.23394.
[39] See Acuity Circles Subcommittee meeting summary, August 12, 2020. Available at https://optn.transplant.hrsa.gov/
[40] 42 CFR §121.8(a)(2).

    - The proposed changes to sorting within liver allocation classifications will further ensure that the most medically urgent candidates are appropriately prioritized for transplant and may decrease waitlist mortality for candidates with a calculated MELD or PELD score as they will be ranked ahead of candidates with a MELD or PELD exception score of the same blood type compatibility and allocation MELD or PELD score.
- **Is designed to…promote patient access to transplantation[41] by** giving similarly situated candidates equitable opportunities to receive an organ offer.
    - This proposal is designed to promote patient access to transplantation by providing more equitable access to specific donor offers for liver transplant candidates with a MELD or PELD exception registered at different transplant programs.
    - The proposal also provides more equitable access to transplant for candidates with a calculated MELD or PELD score compared to candidates with a MELD or PELD exception score.

This proposal mitigates the effect of the candidate's place of residence or place of listing, because the proposal is designed to provide MELD exception scores based on transplants performed in the area around the donor hospital. All exception candidates on a match run will be provided an exception score relative to the same MMaT regardless of where they are listed. This proposal does not impact the use of distance between the donor hospital and transplant program already utilized in liver allocation policy. The change to sorting within liver allocation classifications is not based on a candidate's place of listing or place of residence.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[42] and it is specific to an organ type, in this case livers.[43]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs, to avoid futile transplants, … and to promote the efficient management of organ placement;

Implementation Considerations

Member and OPTN Operations

This proposal will need to be programmed and the implementation timeframe will be based on the specific programming requirements.

The Final Rule requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[44] The Committee discussed two transitional procedures as part of the proposal. First, the Committee discussed what cohort for calculating MMaT should be used upon implementation – the cohort used for the previous MMaT update or an updated cohort that aligns with the implementation date. The Committee determined that when the proposal is implemented, the cohort used to calculate the MMaT for each donor hospital should be based on the date the proposal is

[41] Id.
[42] 42 CFR §121.8(a)(3).
[43] 42 CFR §121.8(a)(4).
[44] 42 CFR §121.8(d).

implemented, not the date that the last MMaT and MPaT update was calculated. When the proposal is implemented, MELD exception scores will be converted from the specific score requested based on the MMaT of the transplant program, to the score relative to the MMaT of donor hospitals. For example, if a candidate has an MELD exception score of 27 that is three points below that MMaT of the transplant program, that score will be converted to be MMaT-3 and will change with each donor hospital. This does not include candidates who have a MELD or PELD exception of 40 or higher. These exception scores are not tied to MMaT or MPaT.

Second, the system does not currently distinguish between time spent at a higher exception or higher calculated score. In this proposal, candidates with a calculated MELD or PELD score are sorted by time at current calculated MELD or PELD score or a higher calculated MELD or PELD score. Time spent at a higher exception score is not included. However, upon implementation, there will be candidates with a calculated MELD or PELD score whose time at current score or higher includes time at a higher exception MELD or PELD score that was accrued prior to implementation. The Committee decided that it was not necessary to distinguish between time at a higher exception MELD or PELD score or time at a higher calculated MELD or PELD score that was accrued prior to implementation. These candidates will be able to keep the time accrued at the higher exception score, but after implementation, time will be restricted to just time at calculated scores. This decision ensures that candidates with a calculated MELD or PELD score who accrued time at a higher exception score are treated no less favorably than under the previous policy because they will keep the previously accrued time at a higher exception score whereas candidates after implementation will only accrue time at a higher lab score.

Operations affecting Histocompatibility Laboratories

There is no expected operational impact on histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

There is no expected operational impact on OPOs.

Operations affecting Transplant Hospitals

The primary operational impact on transplant hospitals involves the updated MMaT calculation being based around the donor hospital. Candidates with an exception will no longer have a static exception score relative to the MMaT of the transplant program where he or she is registered. Instead, exception candidates will have a MELD or PELD score adjustment. For PELD candidates, this adjustment will still be relative to the national MPaT. For MELD candidates, the adjustment will be relative to the MMaT of the donor hospital where a match is being run. This means that MELD exception scores will fluctuate based on the MMaT of the donor hospital and the specific score will not be known until the match is run.

Transplant program staff will need to be prepared to inform exception candidates that they do not have a specific exception score, but an exception relative to the MMaT or MPaT.

Operations affecting the OPTN

The proposed changes will need to be programmed into UNet. The OPTN will continue to be responsible for updating the MMaT score on a bi-annual basis. The OPTN will distribute a policy notice to inform members of all approved policy changes following final Board action (Board consideration of the final proposal is currently planned for June 2021), and system notices will be used to communicate when

system changes are scheduled and these policy changes will be implemented. The OPTN will also create educational materials to support these proposed changes.

Potential Impact on Select Patient Populations

This proposal has the potential to impact a number of select patient populations. The Committee decided not to model the proposal as the Liver Simulate Allocation Model (LSAM) cannot periodically update the MMaT during a multi-year simulation run. An LSAM simulation would be based on prior acceptance behavior and would not be able to show specific changes to waitlist outcomes due to the nature of the proposal. Based on this information, the proposed changes are unlikely to show an impact on waitlist metrics in the LSAM and the Committee decided that modeling would not be useful.[45]

It is probable that candidates with a MELD or PELD exception may see lower access to transplant, as they will be ranked behind candidates with a calculated MELD or PELD score who have the same MELD or PELD score and blood type compatibility. The extent of this impact was not quantified.

It is known that a large portion of pediatric candidates are transplanted with an exception.[46] The OPTN Pediatric Transplantation Committee has expressed concern that the ranking of candidates with a calculated MELD or PELD ahead of MELD or PELD exception candidates of the same MELD or PELD score and blood type compatibility could disproportionately impact pediatric candidates, especially for non-DCD donors age 18-69. This proposal does not impact the priority that pediatric candidates have in allocation policy for pediatric and adolescent donors. The specific impact of the proposal on pediatric candidates was not quantified.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is no expected fiscal impact for OPOs.

Projected Impact on Transplant Hospitals

There should be minimal or no fiscal impact to hospitals.

Projected Impact on the OPTN

Preliminary estimates indicate that this would be an enterprise effort, as over 6,100 hours may be needed for IT programming, communication, and ongoing monitoring. This is estimated to be a larger

[45] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at https://optn.transplant.hrsa.gov/

[46] In the first six months after implementation of the AC policy, 36.4% of pediatric candidates age 0-11 years were transplanted with an exception. In the same timeframe, 55% of pediatric candidates age 12-17 years were transplanted with an exception. For adult candidates (age 18 and higher), only 19.9% of transplant recipients had an exception.

effort than the *Liver and Intestine Distribution Using Distance from Donor Hospital* (estimated at 4,470 hours) that was approved by the Board in 2018.[47]

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[48]

The proposed language will not change the current routine monitoring of OPTN members because these policy changes address candidates' exception score values and candidate sorting on the match run.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[49] To assess the effect of these changes to the calculation of median MELD at transplant, the UNOS Research Department will analyze a number of relevant outputs in a pre vs. post analysis. Such analyses will be performed at approximately 6 months, 1 year, and 2 years post-implementation. National results will be provided and some analyses will be stratified by various geographic units, specialty board type (i.e., Adult HCC, Adult Other Diagnosis, and Pediatric), and other features as appropriate.

Questions of interest:

- Are non-exception and exception transplant candidates ranked with one another appropriately?
- Do exception candidates across the country have more equitable access to transplant, compared to one another?

Relevant analyses:

- Waiting list dropout rates, defined as removal due to death or too sick to transplant, by exception type (no exception, HCC exception, non-HCC exception)
- Waiting list transplant rates by exception type
- Count and percent of the waiting list by exception type
- Distribution of score adjustment requested for MELD or PELD exception requests
- Count and percent of MELD or PELD exception requests approved
- Count and percent of deceased donor transplant recipients by exception type
- Distribution of allocation MELD or PELD score or status at transplant by exception type
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

[47] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at https://optn.transplant.hrsa.gov/
[48] 42 CFR §121.8(a)(7).
[49] 42 CFR §121.8(a)(6).

Conclusion

This proposal improves equity in access to individual donor offers for exception candidates and better aligns the geographic units used in the calculation of MMaT with the geographic units used in liver allocation. In this proposal, MMaT will be calculated for every donor hospital and exception candidates will all be assigned an exception score relative to the MMaT for the donor hospital where the donor is located. In addition, the proposal changes how candidates are sorted within liver allocation classifications. When MELD or PELD score and blood type compatibility are equal, candidates with a calculated MELD or PELD score will be ranked ahead of candidates with a MELD or PELD exception. Candidates with a calculated MELD or PELD score will then be sorted by time at current calculated score or higher calculated score. Exception candidates will be sorted based on time since submission of earliest approved or assigned exception request.

Policy and Guidelines Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

National Liver Review Board Operational Guidelines

1. Overview

The purpose of the National Liver Review Board (NLRB) is to provide fair, equitable, and prompt peer review of exceptional candidates whose medical urgency is not accurately reflected by the calculated MELD or PELD score. The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency of the candidate as compared to other candidates with the same MELD or PELD score adjustment or specific MELD or PELD score.

The NLRB is comprised of specialty boards, including:

- Adult Hepatocellular Carcinoma (HCC)
- Adult Other Diagnosis
- Pediatrics, which reviews requests made on behalf of any candidate registered prior to turning 18 years old and adults with certain pediatric diagnoses

The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the Chair of the NLRB for a two year term.

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

A

Active candidate
A candidate on the waiting list who is currently suitable for transplantation and eligible to receive organ offers.

Agent
A person legally authorized to act on behalf of another person.

Allocation MELD or PELD Score
The highest exception or calculated MELD or PELD score available to the candidate at the time of the match run for a liver or liver-intestine according to Policy. Allocation MELD or PELD score includes liver-intestine points.

Alternative allocation system
A type of variance that allows members who are permitted to join the variance to allocate organs differently than the OPTN Policies.

Alternative local unit (ALU)
A type of variance that creates a distinct geographic area for organ procurement and distribution.
Alternative point assignment system
A type of variance that allows members who are permitted to join the variance to assign points for organ allocation differently than required by the OPTN Policies.
Antigen mismatch
An antigen mismatch occurs when an identified deceased or living donor antigen is not recognized as equivalent to the recipient's own antigens. In cases where a donor or candidate only has one antigen identified at a human leukocyte antigen (HLA) locus (A, B, or DR), the antigens are considered to be identical at that locus.

Approved MELD or PELD Exception
A MELD or PELD exception or exception extension that met standardized criteria in OPTN policy or was reviewed and approved by the NLRB

Assigned MELD or PELD Exception
A MELD or PELD exception or exception extension where the NLRB failed to make a decision within 21 days of the date of submission of the request and the candidate was assigned the requested score.
Authorization
The act of granting permission for a specific act. This is sometimes called consent, which is not to be confused with informed consent.

M

Match
A donor and the donor's matched candidate. This includes deceased, living, and KPD donors.

~~**Match MELD or PELD Score**~~
~~The MELD or PELD score available to the candidate at the time of the match for a deceased donor liver or liver-intestine.~~

Policy 9: Allocation of Livers and Liver-Intestines

9.4 MELD or PELD Score Exceptions

If a candidate's transplant program believes that a candidate's current MELD or PELD score does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may submit a MELD or PELD score exception request to the National Liver Review Board (NLRB).

9.4.A MELD or PELD Score Exception Requests

A MELD or PELD score exception request must include ~~*all* the following~~:

1. A request for ~~a specific MELD or PELD score~~ either:

a. An adjustment of a certain amount of points higher or lower than MMaT or MPaT or
b. A specific MELD or PELD score of 40 or higher

2. ~~A justification of how the medical criteria supports that the candidate has a higher MELD or PELD score~~
3. ~~An explanation of how the candidate's current condition is comparable to that of other candidates with that MELD or PELD score~~

2. A justification that outlines how a candidate's medical condition warrants an exception and the specific score being requested.

~~Approved~~ MELD or PELD exceptions ~~scores~~ are valid for 90 days from the date the exception is approved or assigned.

9.4.C MELD or PELD Score Exception Extensions

9.4.C.ii Other MELD or PELD Score Exception Extensions

A candidate's approved or assigned exception will be maintained if the transplant ~~hospital~~ program enters a MELD or PELD Exception Score Extension Request before the due date, even if the NLRB does not act before the due date. If the extension request is denied or if no MELD or PELD Exception Score Extension Request is submitted before the due date, then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

Each approved or assigned MELD or PELD exception extension is valid for an additional 90 days beginning from the day that the previous exception or extension expired.

9.4.D Calculation of Median MELD or PELD at Transplant

~~Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 nautical miles of the candidate's listing hospital in a prior 365 day period.~~

~~Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation.~~

~~The MMaT and MPaT calculations exclude recipients who are either of the following:~~

~~1. Transplanted with livers from living donors, DCD donors, and donors from donor hospitals more than 500 nautical miles away from the transplant hospital~~
~~2. Status 1A or 1B at the time of transplant.~~

~~The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The updated cohort will include transplants over a prior 365 day period. If there have been fewer than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the cohort, the MMaT will be calculated based on a total of a 730 day period.~~

For each donor hospital, the OPTN will calculate the MMaT based on a cohort of recipients transplanted at programs at or within 150 nautical miles of the donor hospital in a prior 365 day period. If there are either less than two active liver transplant programs or less than 10 qualifying transplants within 150 nautical miles of the donor hospital, the geographic area used to calculate the MMaT will increase in 50 nautical mile increments until two active liver transplant programs and 10 qualifying transplants are included in the MMaT cohort.

The MMaT is calculated by using the median of the MELD scores at the time of transplant of all recipients within the geographic area defined above that are at least 12 years old at the time of transplant. Recipients are excluded who are either of the following:

1. Transplanted with livers from living donors, DCD donors, or donors from donor hospitals more than 500 nautical miles away from the recipient's transplant program or
2. Status 1A or 1B at the time of transplant.

If a transplant program has not performed at least one transplant included in the MMaT calculation, the program is not included in the MMaT cohort.

If there are less than 10 qualifying transplants within 250 nautical miles of a donor hospital in Hawaii or Puerto Rico, the MMaT will be calculated based on a total of 730 days. There does not need to be two transplant programs within 250 nautical miles of donor hospitals in Hawaii or Puerto Rico.

Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old at the time of transplant in the nation. Recipients are excluded who are either of the following:

1. Transplanted with livers from living donors, DCD donors, or donors from donor hospitals more than 500 nautical miles away from the recipient's transplant program or
2. Status 1A or 1B at the time of transplant.

The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The updated cohort will include transplants over a prior 365 day period.

9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant

A match run will provide MELD exception candidates on the match run a MELD exception score relative to the MMaT for the donor hospital. PELD exception candidates are provided a PELD exception score relative to the MPaT for the nation. If a candidate's exception score relative to MMaT or MPaT would be lower than 15, the candidate's exception score will be 15.

~~Exceptions scores will be updated to reflect changes in MMaT or MPaT each time the MMaT or MPaT is recalculated.~~ The following exception scores are not awarded relative to MMaT or MPaT ~~and will not be updated~~:

1. Exception scores of 40 or higher awarded by the NLRB according to *Policy 9.4.A: MELD or PELD Score Exception Requests*
2. Any exception awarded according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions*

3. Exceptions awarded to candidates less than 18 years old at time of registration according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*
4. ~~Initial exceptions and first extensions awarded to candidates at least 18 at time of registration according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*~~

9.5 Specific Standardized MELD or PELD Score Exceptions

Candidates are eligible for MELD or PELD score exceptions or extensions that do not require evaluation by the NLRB if they meet *any* of the following requirements for a specific diagnosis of *any* of the following:

- Cholangiocarcinoma (CCA), according to *Policy 9.5.A: Requirements for Cholangiocarcinoma MELD or PELD Score Exceptions*
- Cystic fibrosis, according to *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions*
- Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions*
- Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions*
- Metabolic disease, according to *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*
- Portopulmonary hypertension, according to *Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions*
- Primary hyperoxaluria, according to *Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions*
- Hepatocellular carcinoma, according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*

~~If a candidate's exception score based on the score assignments relative to MMaT or MPaT in this section would be lower than 15, the candidate's exception score will be 15.~~

9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for CCA, if the candidate's transplant ~~hospital~~ program meets *all* the following qualifications:

1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include *all* of the following:
   - Candidate selection criteria
   - Administration of neoadjuvant therapy before transplantation

- Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
- Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and at least *one* of the following:
   - Biopsy or cytology results demonstrating malignancy
   - Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
   - Aneuploidy

   The tumor must be considered un-resectable because of technical considerations or underlying liver disease.
3. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a mass, the mass must be single and less than three cm.
4. Documents the exclusion of intrahepatic and extrahepatic metastases by cross-sectional imaging studies of the chest and abdomen within 90 days prior to submission of the initial exception request.
5. Assesses regional hepatic lymph node involvement and peritoneal metastases by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) must be avoided because of the high risk of tumor seeding associated with these procedures.

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive a score according to *Table 9-2* below.

Table 9-2: CCA Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions,* and provide cross-sectional imaging studies of the chest and abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging studies must have been completed within 30 days prior to the submission of the extension request.

9.5.B Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for cystic fibrosis if the candidate's diagnosis has been confirmed by genetic analysis, and the candidate has a forced expiratory

volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to submission of the initial exception request.

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive a score according to *Table 9-3* below.

Table 9-3: Cystic Fibrosis Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.C Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for FAP if the candidate's transplant ~~hospital~~ program submits evidence of *all* of the following:

1. Either that the candidate is also registered and active on the waiting list for a heart transplant at that transplant hospital, or has an echocardiogram performed within 30 days prior to submission of the initial exception request showing the candidate has an ejection fraction greater than 40 percent.
2. That the candidate can walk without assistance.
3. That a transthyretin (TTR) gene mutation has been confirmed.
4. A biopsy-proven amyloid.

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive a score according to *Table 9-4* below.

Table 9-4: FAP Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions* and meet one of the following criteria:

1. An echocardiogram that shows that the candidate has an ejection fraction greater than 40 percent within the last 120 days

2. Registered and active on the waiting list for a heart transplant at that hospital

9.5.D Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions

A candidate will receive a MELD score exception for HAT if the candidate is at least 18 years old at registration and has HAT within 14 days of transplant but does not meet criteria for status 1A in *Policy 9.1.A: Adult Status 1A Requirements*.

Candidates who meet these requirements will receive a MELD score of 40.

In order to be approved for an extension of this MELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.E Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for HPS if the candidate's transplant ~~hospital~~ program submits evidence of *all* of the following:

1. Ascites, varices, splenomegaly, or thrombocytopenia.
2. A shunt, shown by either contrast echocardiogram or lung scan.
3. PaO_2 less than 60 mmHg on room air within 30 days prior to submission of the initial exception request.
4. No clinically significant underlying primary pulmonary disease.

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive a score according to *Table 9-5* below.

Table 9-5: HPS Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions,* with evidence that the candidate's PaO_2 remained at less than 60 mmHg on room air within the 30 days prior to submission of the extension request.

9.5.F Requirements for Metabolic Disease MELD or PELD Score Exceptions

A liver candidate less than 18 years old at the time of registration will receive a MELD or PELD score exception for metabolic disease if the candidate's transplant ~~hospital~~ program submits evidence of urea cycle disorder or organic acidemia.

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive a score according to *Table 9-6* below.

Table 9-6: Metabolic Disease Exception Scores

Age	Age at registration	Score
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

If the candidate does not receive a transplant within 30 days of being registered with the exception score, then the candidate's transplant physician may register the candidate as a status 1B.

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.G Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for portopulmonary hypertension if the transplant ~~hospital~~ program submits evidence of *all* of the following:

1. Document via heart catheterization initial mean pulmonary arterial pressure (MPAP) level greater than or equal to 35 mmHg and initial pulmonary vascular resistance (PVR) level greater than or equal to 240 dynes*sec/cm^5 (or greater than or equal to 3 Wood units (WU)). These values must be from the same test date.
2. Other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor
3. Initial transpulmonary gradient to correct for volume overload
4. Documentation of treatment
5. Document via heart catheterization within 90 days prior to submission of the initial exception either of the following:
    - Post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400 dynes*sec/cm^5 (or less than 5 Wood units (WU)). These values must be from the same test date.
    - Post-treatment MPAP greater than or equal to 35 mmHg and less than 45 mmHg and post-treatment PVR less than 240 dynes*sec/cm^5 (or less than 3 Wood units (WU)). These values must be from the same test date.
6. Documentation of portal hypertension at the time of initial exception

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive a score according to *Table 9-7* below.

Table 9-7: Portopulmonary Hypertension Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions* with evidence of a heart catheterization since the last exception or extension request that confirms either of the following:

- MPAP less than 35 mmHg and PVR less than 400 dynes*sec/cm^5 (or less than 5 Wood units (WU)). These values must be from the same test date.
- MPAP greater than or equal to 35 mmHg and less than 45 mmHg and PVR less than 240 dynes*sec/cm^5 (or less than 3 Wood units (WU)). These values must be from the same test date.

9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the candidate's transplant ~~hospital~~ program submits evidence of all of the following:

1. The liver candidate is registered on the waiting list for a kidney transplant at that transplant hospital
2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis
3. Estimated glomerular filtration rate (eGFR) by six variable Modification of Diet in Renal Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or iohexol, is less than or equal to 25 mL/min on 2 occasions at least 42 days apart

A candidate who meets the requirements for a standardized MELD or PELD score exception will ~~be assigned~~ receive an exception score according to *Table 9-8* below.

Table 9-8: Primary Hyperoxaluria Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	Equal to MMaT
At least 12 years old	Less than 18 years old	3 points above MMaT
Less than 12 years old	Less than 12 years old	3 points above MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to Policy 9.4.C: MELD or PELD Score Exception Extensions with evidence that the candidate is registered on the waiting list for a kidney transplant at that hospital.

9.5.I Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) will ~~be provided~~ receive a score according to Policy *9.5.I.vii: Extensions of HCC Exceptions* if the candidate meets the criteria according to *Policies 9.5.I.i through 9.5.I.vi.*

9.5.I.vii Extensions of HCC Exceptions

A candidate with an approved exception for HCC is eligible for automatic approval of an extension if the transplant program enters a MELD or PELD Exception Score Extension Request that contains the following:

1. Documentation of the tumor using a CT or MRI
2. The type of treatment if the number of tumors decreased since the last request
3. The candidate's alpha-fetoprotein (AFP) level

The candidate's exception extension will then be automatically approved unless *any* of the following occurs:

- The candidate's lesions progress beyond T2 criteria, according to *9.5.I.ii: Eligible Candidates Definition of T2 Lesions*
- The candidate's alpha-fetoprotein (AFP) level was less than or equal to 1,000 ng/mL on the initial request but subsequently rises above 1,000 ng/mL
- The candidate's AFP level was greater than 1,000 ng/mL, the AFP level falls below 500 ng/mL after treatment but before the initial request, then the AFP level subsequently rises to greater than or equal to 500 ng/mL
- The candidate's tumors have been resected since the previous request
- The program requests a score different from the scores assigned in Table 9-10.

When a transplant program submits either an initial exception request or the first extension request for a liver candidate at least 18 years old at the time of registration ~~submits an initial request or the first extension request~~ that meets the requirements for a standardized MELD score exception, the candidate will ~~receive a MELD score of 6, and~~ appear on the match run according to ~~that exception score or~~ the calculated MELD score~~, whichever is higher.~~.

A candidate who meets these requirements for a MELD or PELD score exception for HCC will ~~be assigned~~ receive a score according to *Table 9-10* below.

Table 9-10: HCC Exception Scores

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	~~6~~ Calculated MELD
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

9.6 Waiting Time

9.6.A Waiting Time for Liver Candidates

Liver transplant candidates on the waiting list accrue waiting time within status 1A or 1B or any ~~assigned~~ MELD or PELD score.

~~A candidate's waiting time at a MELD or PELD score equals the sum of *all* the following:~~

~~1. Waiting time at current MELD or PELD score~~
~~2. Previous waiting time accrued during an earlier period at current MELD or PELD score~~
~~3. Previous total waiting time accrued at any MELD or PELD score higher than the current MELD or PELD score~~
~~4. Previous total waiting time accrued at status 1A and status 1B~~

Status 1A or 1B candidates will receive waiting time points based on their waiting time in that status, according to *Policy 9.7.A: Points for Waiting Time*. Status 1A candidates begin accruing waiting time at status 1A upon submission of the earliest *Liver Status 1A or 1B Justification Form* for status 1A. Status 1B candidates begin accruing waiting time at status 1B upon submission of the earliest *Liver Status 1A or 1B Justification Form* for status 1B.

Candidates with a MELD or PELD score begin accruing waiting time when the candidate is first registered as an active liver candidate on the waiting list.

Allocation MELD or PELD score waiting time is accrued as follows:

- If the candidate's allocation MELD or PELD score is a calculated MELD or PELD score, then allocation MELD or PELD score waiting time includes all waiting time at current or higher calculated MELD or PELD score. Waiting time at current or higher calculated MELD or PELD score includes *all* of the following:
    1. Waiting time at current calculated MELD or PELD score
    2. Previous waiting time accrued during an earlier period at current calculated MELD or PELD score
    3. Previous total waiting time accrued at any calculated MELD or PELD score higher than the current calculated MELD or PELD score
    4. Previous total waiting time accrued at status 1A and status 1B
- If the candidate's allocation MELD or PELD score is an exception MELD or PELD score, then allocation MELD or PELD score waiting time equals time since submission of earliest approved or assigned MELD or PELD exception request.

9.8 Liver Allocation, Classifications, and Rankings

Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate's ~~match~~ allocation MELD or PELD score.

9.8.D Sorting Within Each Classification

Within each status 1A allocation classification, candidates are sorted in the following order:

1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
2. Total waiting time at status 1A (highest to lowest)

Within each status 1B allocation classification, candidates are sorted in the following order:

1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
2. Total waiting time at status 1B (highest to lowest)

Within each MELD or PELD score allocation classification, all candidates are sorted in the following order:

1. Allocation MELD or PELD score (highest to lowest)
2. ~~Identical blood types, compatible blood types, then incompatible blood types~~
3. ~~Waiting time at the current or higher MELD or PELD score (highest to lowest)~~
4. ~~Time since submission of initial approved MELD or PELD exception request (highest to lowest)~~
2. Blood type compatibility (identical, compatible, then incompatible)
3. Allocation MELD or PELD score type (calculated then exception)
4. Allocation MELD or PELD score waiting time (highest to lowest)
5. Total waiting time (highest to lowest)

OPTN

Public Comment Proposal

Updating National Liver Review Board Guidance and Policy Clarification

OPTN Liver and Intestinal Organ Transplantation Committee

Prepared by: Matt Cafarella, MPH
UNOS Policy and Community Relations Department

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Updating National Liver Review Board Guidance and Policy Clarification

Affected Policy:	*Policy 9.5.A: Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions*
Affected Guidance:	*Guidance to Liver Transplant Programs and the National Liver Review Board for Pediatric MELD or PELD Exception Review* *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review*
Sponsoring Committee:	*Liver and Intestinal Organ Transplantation*
Public Comment Period:	*January 21, 2021 – March 23, 2021*

Executive Summary

The purpose of the National Liver Review Board (NLRB), which was implemented on May 14, 2019, is to provide equitable access to transplant for liver candidates whose calculated model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency.[1] Since implementation, the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) has regularly evaluated the NLRB to identify opportunities for improvement. This proposal is the latest in a series of enhancements made to the NLRB after implementation.

This proposal seeks to make improvements to the NLRB policy and guidance documents. Specifically, the proposal adds one diagnostic criterion to the requirements for a candidate to be eligible for a standardized exception for cholangiocarcinoma (CCA) in OPTN policy. It also updates the guidance for pediatric exceptions, the guidance for candidates with neuroendocrine tumors (NET), and the guidance for candidates with primary sclerosing cholangitis (PSC) or secondary sclerosing cholangitis (SSC). The updates to NLRB guidance will ensure that all candidates are appropriately reviewed for MELD or PELD exceptions.

The Committee is seeking public comment feedback on the proposed changes listed above.

The Committee submits the following proposal for Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[2]

[1] *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at https://optn.transplant.hrsa.gov/

[2] 42 CFR §121.4(a)

Background

When being listed for a liver transplant, candidates receive a calculated MELD or PELD score, which is based on a combination of the candidate's clinical lab values.[3] These scores are designed to reflect the probability of death on the waitlist within a 3-month period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned status 1A or 1B.

When a transplant program believes that a candidate's calculated MELD or PELD score does not accurately reflect a candidate's medical urgency, they may request a score exception. The NLRB is responsible for reviewing exception requests and either approving or denying the requested score.

The NLRB was approved by the OPTN Board of Directors (the Board) at their June 2017 meeting and was implemented on May 14, 2019.[4] The NLRB was designed to create an efficient and equitable system for reviewing exception requests for candidates across the country.

The Committee is committed to continuously improving the NLRB to ensure the system functions efficiently and policy and guidance remain relevant and accurate. The OPTN Board of Directors (the Board) has previously approved a number of enhancements to the NLRB and the changes included in this proposal continue the effort of the Committee to improve the NLRB.[5,6]

Purpose

The purpose of this proposal is to build upon previous enhancements and continue to improve the NLRB by incorporating feedback from the transplant community. The proposed changes are anticipated to create a more efficient and equitable system for the review of exception requests.

The enhancements included in this proposal involve changes to OPTN policy language and the NLRB guidance documents. The guidance documents are intended to provide guidance to review board members and transplant programs to help ensure consistent and equitable review of exception cases. The guidance documents are not OPTN policy and serve as a resource for reviewers and transplant programs. Each of the three specialty review boards (Pediatric, Adult Other Diagnosis, and Adult Hepatocellular Carcinoma (HCC) has a specific guidance document. The Committee is proposing changes to the guidance documents for the Pediatric specialty review board and the Adult Other Diagnosis specialty review board.

[3] The calculation for the MELD and PELD scores can be found in OPTN Policy, Available at https://optn.transplant.hrsa.gov/.
[4] *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at https://optn.transplant.hrsa.gov/
[5] *Enhancements to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2020, Available at https://optn.transplant.hrsa.gov/
[6] *Further Enhancements to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2020, Available at https://optn.transplant.hrsa.gov/

The Committee submits the following proposal for Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[7]

Overview of Proposal

OPTN Policy: Hilar CCA Standardized Exception Criteria

The Committee is proposing one minor addition to OPTN policy as part of this proposal. Under the NLRB, candidates who meet the criteria outlined in OPTN policy for one of the nine standardized diagnoses are eligible to have their initial exception request or extension requests automatically approved. One such diagnosis is hilar CCA.

In addition to meeting a number of other criteria, candidates are automatically approved for a CCA exception if the transplant program documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiopathy and at least one of the following:

1. Biopsy or cytology results demonstrating malignancy
2. Carbohydrate antigen 19-9 greater than 100 U/ml in absence of cholangitis
3. Aneuploidy

In addition, the tumor must be considered un-resectable because of technical considerations or underlying liver disease.

This policy was approved by the Board in June 2009 and was implemented in November 2011.[8] However, the Committee recently identified that the presence of an associated hilar mass less than or equal to three centimeters (cm) as a diagnostic criteria for CCA was absent from current policy, causing candidates meeting this diagnostic criteria to be reviewed by the NLRB instead of automatically approved. A liver transplant candidate can also meet the diagnostic criteria for hilar CCA with a malignant appearing stricture and the presence of an associated hilar mass that is less than or equal to three cm in radial diameter.[9] The Committee is proposing the addition of this to the list of diagnostic criteria included above. This addition ensures that all candidates meeting the diagnostic criteria for hilar CCA are eligible to receive a standardized exception, as long as the candidates meets the remaining criteria in policy. The proposed addition will allow more candidates to meet standardized criteria and reduce the number of exception cases reviewed by the Adult Other Diagnosis specialty board.

The Committee is seeking public comment on the proposed addition to the diagnostic criteria for hilar CCA.

[7] 42 CFR §121.4(a)

[8] *OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Report to the Board of Directors*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2009

[9] Sarwa Darwish Murad et al., "Efficacy of Neoadjuvant Chemoradiation, Followed by Liver Transplantation, for Perihilar Cholangiocarcinoma at 12 US Centers," *Gastroenterology* 143, no. 1 (July 2012): 88-98.e3, https://doi.org/10.1053/j.gastro.2012.04.008.

Guidance Documents

The proposal includes updates to the guidance documents for the Pediatric specialty review board and the Adult Other Diagnosis specialty review board.

Pediatric Guidance

The proposal includes updates to a number of areas of guidance for the Pediatric Specialty Board including:

- Growth failure or nutritional insufficiency
- Complications of portal hypertension, including ascites and gastrointestinal bleeding
- Metabolic liver disease
- Conclusion

These changes are based on a survey conducted by the Society of Pediatric Liver Transplantation (SPLIT) in 2019 and were developed in conjunction with the OPTN Pediatric Transplantation Committee.

Growth Failure and Nutritional Insufficiency

Growth failure is included in the current PELD calculation, which provides additional PELD points for candidates that are more than two standard deviations below the candidate's expected growth based on age and gender using the most recent Center for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart. Despite the inclusion of growth failure in the PELD calculation, growth failure remains the most common reason for PELD exceptions.[10] In addition, recent research has shown that the manner in which growth failure is incorporated into the current PELD calculation may not adequately provide additional PELD points to all candidates with growth failure. Some candidates fall into a "growth failure gap," in which their current weight or height is more than two standard deviations below expected for their current age, but they are above the PELD threshold for additional points.[11] An effort is underway to revise the PELD score, but in the meantime, growth failure remains inadequately captured by the current PELD calculation in some cases.[12]

Growth failure has been repeatedly noted as a risk factor for poor outcomes in liver transplant candidates, both before and after transplant.[13] However, current guidance on growth failure states that there is insufficient evidence to support approval for exception points for candidates with growth failure or nutritional insufficiency. The Committee is proposing updates to the guidance for growth failure and nutritional insufficiency based on the fact that research suggests it is not adequately accounted for in the current PELD calculation and it remains an important risk factor for poor waitlist outcomes. More so,

[10] E. R. Perito et al., "Justifying Nonstandard Exception Requests for Pediatric Liver Transplant Candidates: An Analysis of Narratives Submitted to the United Network for Organ Sharing, 2009-2014," *American Journal of Transplantation* 17, no. 8 (February 28, 2017): 2144–54, https://doi.org/10.1111/ajt.14216.

[11] Sonja M. Swenson et al., "Impact of the Pediatric End-Stage Liver Disease (PELD) Growth Failure Thresholds on Mortality among Pediatric Liver Transplant Candidates," *American Journal of Transplantation* 19, no. 12 (September 3, 2019): 3308–18, https://doi.org/10.1111/ajt.15552.

[12] The Committee is in the process of developing a proposal to improve the PELD score and has discussed updating how growth failure is defined as part of that effort.

[13] Sonja M. Swenson et al., "Impact of the Pediatric End-Stage Liver Disease (PELD) Growth Failure Thresholds on Mortality among Pediatric Liver Transplant Candidates," *American Journal of Transplantation* 19, no. 12 (September 3, 2019): 3308–18, https://doi.org/10.1111/ajt.15552.

current guidance is relatively restrictive regarding which candidates should be considered for an exception due to growth failure or nutritional insufficiency.

First, the Committee is proposing the removal of a sentence stating that there is insufficient evidence to support approval of exception points for pediatric candidates with growth failure or nutritional insufficiency. The updated guidance includes a sentence that acknowledges the current PELD calculation does not adequately capture growth failure for all children. This change reflects the recent research showing the presence of a "growth failure gap," in which candidates do not meet the growth failure threshold in the PELD calculation but have an increased risk of waitlist mortality similar to those children meeting the growth failure criteria.[14]

In addition, current guidance is restricted to candidates over one year of age. However, candidates under one year of age are disproportionately impacted by the "growth failure gap" and should be provided a pathway to PELD exception points.[15] The proposed revision removes the age over one criteria.

The proposed changes also include a clarification for the z-score used to identify candidates who should be considered for a PELD exception. Previous guidance was unclear on which candidates met the criteria for being less than two standard deviations below the mean for age and gender. The proposal provides more detail on the anthropometric measurements that can be used to determine if a candidate should be considered for a PELD exception. Current guidance only includes skin fold thickness but the proposed change includes triceps skin fold thickness or mid-arm muscle circumference. This change aligns with standard anthropometric measurement practices in pediatric clinical care.

The proposed changes to the guidance for growth failure and nutritional insufficiency will ensure that candidates whose growth failure or nutritional insufficiency is not adequately captured by the PELD score are appropriately considered for exceptions.

The Committee is seeking public comment feedback on the proposed changes to the guidance for growth failure and nutritional insufficiency.

Complications of portal hypertension, including ascites and gastrointestinal bleeding

The current guidance document for the Pediatric Specialty Board includes recommendations for candidates with complications of portal hypertension, including ascites and gastrointestinal bleeding. The Committee is proposing a number of updates to this section of guidance based on feedback received from the pediatric transplant community. The proposed changes include more detail on what information should be included in exception requests for candidates in certain clinical situations and the addition of guidance for candidates requiring a hospitalization of at least five days with ascites not adequately controlled by oral diuretics and requiring IV diuretic therapy.

First, the Committee is proposing the addition of language that outlines what information should be submitted when applying for an exception for a candidate with gastrointestinal bleeding with ongoing transfusion requirement. This suggestion was brought forth through the SPLIT survey and based on feedback from the Pediatric Committee. They noted that when applying for such exceptions, reviewers

[14] Ibid.
[15] Ibid.

often request more information on the types of treatment or reasons that certain treatment options were not attempted. The Committee did make clear that reviewers should not be providing treatment recommendations in their comments, but it would be helpful to include some information as part of the initial exception request so that reviewers have a complete understanding of the candidate's clinical situation.[16] Therefore, the Committee is proposing the addition of language that encourages transplant programs to include the interventions and treatments attempted, or the contraindications to their use, and the amount and dates of transfusions attempted in exception requests for candidates with gastrointestinal bleeding. The Committee is also proposing the removal of language suggesting that transplant programs provide information on placement of transjugular intrahepatic portosystemic shunts (TIPS) or ongoing octreotide administration, as these would be included in the proposed new language.

The purpose of the additional language is to provide the NLRB reviewers with all pertinent information for the candidate and reduce the number of exceptions for gastrointestinal bleeding that are denied because such information is not provided.

The Committee is proposing a similar addition for candidates who have serum sodium less than 130 g/dL on two occasions more than two weeks apart. Current guidance includes a recommendation that candidates with severe or complicated ascites and serum sodium less than 130 g/dL on two occasions more than two weeks apart should be considered for an exception. However, the Committee is proposing the addition of language that suggests transplant programs specify the dates, values, and treatment in order to demonstrate the persistence and severity. This new language is intended to give more direct guidance to transplant programs on what information to include in exception requests for these candidates. The purpose is to ensure that NLRB reviewers have all relevant information and decrease the number of exception requests that are denied because they are lacking necessary information.

In addition, current pediatric guidance includes recommendations for candidates with severe or complicated ascites with either multiple therapeutic paracenteses or hydrothorax requiring chest tube or therapeutic thoracenteses. However, current guidance specifically states that the candidate must have at least two therapeutic paracenteses in the previous 30 days, not including diagnostic paracentesis. There is no similar specificity provided for therapeutic thoracentesis. The Committee is proposing the addition of language that states a candidate should have at least two thoracenteses in the last 60 days not including the diagnostic thoracentesis. This change was first proposed by the SPLIT survey and members of the Pediatric Committee. The purpose is to provide similar guidance for candidates with paracenteses and thoracenteses and ensure that the appropriate candidates are considered for an exception. The Committee decided to change the timeframe for the two thoracenteses to be in the previous 60 days, as opposed to the previous 30 days, because thoracenteses procedures in pediatric candidates are riskier and are typically done in candidates with higher risk of waitlist mortality.[17]

The final proposed change to this section of the guidance document is the addition of language that recommends an exception for candidates requiring a hospitalization of at least five days with ascites not adequately controlled by oral diuretics and requiring IV diuretic therapy. Current guidance states that candidates with ascites adequately controlled by diuretics in the outpatient setting should not be

[16] See NLRB Subcommittee meeting summary, July 9, 2020. Available at https://optn.transplant.hrsa.gov/
[17] See NLRB Subcommittee meeting summary, July 9, 2020. Available at https://optn.transplant.hrsa.gov/

considered for an exception, but there is no guidance for candidates who are hospitalized and requiring IV diuretic therapy. The Committee agreed that it is rare for pediatric candidates to be admitted for ascites requiring IV diuretics but that these candidates should be considered for a higher MELD or PELD score as the candidates have increased medical urgency for transplantation.[18] The Committee felt that recommending a hospitalization of five days would ensure that the candidate is sick enough to warrant an exception and preclude any transplant programs from admitting a candidate for a brief amount of time just to get an exception.[19]

The Committee is seeking feedback on the proposed changes listed above, but is specifically interested in feedback on the proposed addition of guidance for candidates admitted with ascites requiring IV diuretic therapy.

Metabolic Liver Disease

In OPTN Policy, pediatric candidates with a metabolic disease are eligible for a standardized exception. If a candidate does not receive a transplant within 30 days of being registered with an exception for a metabolic disease, the candidate is eligible to be listed as status 1B. However, the only metabolic diseases that qualify for the standardized exception, and therefore as status 1B, are urea cycle disorders and organic acidemias.

Since implementation of the NLRB, members of the pediatric community have noted that there are other metabolic disorders that may be appropriate for exception points. These diagnoses are rare, but it is important that guidance exists for transplant programs and reviewers when such a diagnosis is present. The Committee is proposing the addition of language to the guidance for the Pediatric specialty board recommending that these candidates be considered for a MELD or PELD exception.

The proposed language notes that an exhaustive list of all metabolic disorders and the exact clinical criteria for all metabolic disorders is impossible to provide, but candidates with a rare metabolic disorder should be able to receive an exception if appropriate. In order to receive an exception for a rare metabolic disorder, the proposed language suggests that transplant programs should describe how liver transplant will address the disease complication or mortality risk, provide references to other comparable diagnoses in guidance to justify the request and the points requested, and include any experience from similar cases that shows how liver transplant was beneficial for the patient.

The purpose of this proposed addition is to ensure that candidates with rare metabolic disorders are provided an opportunity to receive an exception when appropriate.

The Committee is seeking public comment feedback on the new language for candidates with rare metabolic liver diseases.

Conclusion

The Committee is proposing an addition to the conclusion section of the pediatric guidance document that allows transplant programs and reviewers to consider additional, pertinent evidence to a candidate's clinical situation, even if it is not explicitly included in guidance. The addition of this language reflects feedback that there may be additional clinical information that is relevant to a

[18] Ibid.
[19] Ibid.

candidate's clinical scenario but falls outside of what is currently included in guidance. The inclusion of this evidence in an exception request should be considered by reviewers as appropriate, even if it is not included in the specific guidance for a certain diagnosis. The language acknowledges that every candidate is unique and it is impossible for the guidance to account for every clinical situation.

The Committee is seeking public feedback on the proposed addition to the conclusion.

Adult Other Diagnosis Guidance

The proposal includes improvements to two areas of Adult Other Diagnosis guidance, NET and PSC/SSC.

Neuroendocrine Tumors (NET)

Current NLRB guidance provides a MELD exception recommendation for candidates with NET. One of the criterion included in the exception guidance is for the candidate to be less than 60 years old. The Committee is proposing that the age less than 60 criterion be removed to allow candidates over the age of 60 to also be considered for a MELD exception if they meet the other criteria in guidance.

The proposed change was initiated by a member of the Committee who noted that a recent candidate listed at his or her transplant program received an exception for NET prior to turning 60 but then had an extension of that exception denied after turning 60. The Committee determined that a candidate should not lose a previously approved exception upon turning 60 and that the age less than 60 threshold should be reviewed as an area for improvement.[20]

The age less than 60 threshold was initially included in guidance due to research available at the time that outlined specific criteria for NET patients who should be considered for liver transplantation.[21] When discussing the criteria, the Committee noted that recipients under the age of 60, regardless of diagnosis, tend to have better post-transplant outcomes as they are younger and generally healthier than older transplant recipients.[22] This fact should not be used as a means to exclude candidates over the age of 60 from receiving a MELD exception. The Committee also noted that the age less than 60 threshold was a relative criteria in the research used to originally develop the guidance.[23]

The Committee reviewed updated data showing that recipients with NET who were over the age of 60 had acceptable post-transplant outcomes, which were similar to those under the age of 60. This data showed that since 2000, there have been 227 recipients transplanted with metastatic NET, 46 of whom (20.3%) had an age greater than or equal to 59. Three of the recipients were excluded for death within 30 days of transplant. Of this subset of recipients, the rate of survival was 95% within one year of transplant, 84% within three years, and 56% within five years.[24]

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[20] See NLRB Subcommittee meeting summary, October 13, 2020. Available at https://optn.transplant.hrsa.gov/

[21] Vincenzo Mazzaferro, Andrea Pulvirenti, and Jorgelina Coppa, "Neuroendocrine Tumors Metastatic to the Liver: How to Select Patients for Liver Transplantation?" *Journal of Hepatology* 47, no. 4 (October 2007): 460–66, https://doi.org/10.1016/j.jhep.2007.07.004.

[22] See NLRB Subcommittee meeting summary, October 13, 2020. Available at https://optn.transplant.hrsa.gov/

[23] Taizo Hibi et al., "Liver Transplantation for Colorectal and Neuroendocrine Liver Metastases and Hepatoblastoma. Working Group Report From the ILTS Transplant Oncology Consensus Conference," *Transplantation* 104, no. 6 (June 2020): 1131–35, https://doi.org/10.1097/tp.0000000000003118.

[24] OPTN data was provided by a Committee member based on liver transplants performed between January 1, 2020 and July 31, 2015. The rates are based on OPTN data as of September 4, 2020.

The Committee is proposing that the age less than 60 threshold be removed from the guidance for NET based on updated data that shows recipients over the age of 60 have acceptable post-transplant outcomes.

The proposed changes also include the removal of language in the guidance that was vague and provided no clear instruction either for transplant programs or reviewers.

The Committee is seeking public comment feedback on the proposed changes to NET guidance.

Primary Sclerosing Cholangitis and Secondary Sclerosing Cholangitis

The Committee is also proposing changes to the guidance for candidates with PSC. Candidates with PSC, which is a chronic liver disease affecting the bile ducts, have historically had lower waitlist mortality rates compared to candidates with other diagnoses and similar MELD scores.[25] As a result, the guidance for PSC is relatively restrictive in recommending a MELD exception for these candidates. However, while candidates with PSC have lower waitlist mortality rates overall, they are prone to additional adverse outcomes such as development of CCA and sepsis due to ascending cholangitis.[26]

During the public comment period from August 2020 to October 2020, the Committee sponsored a public comment proposal titled, *Further Enhancements to the National Liver Review Board.*[27] The majority of public comment feedback received on this proposal related to the current guidance for PSC. Many of the comments came from candidates or family members of candidates with PSC, asking the Committee to reconsider the MELD exception guidance for PSC.[28] However, there were no proposed changes included in that proposal related to PSC guidance. As a result of the influx of comments, the Committee decided to review the PSC guidance.

Currently, the guidance states that most patients with PSC do not require a MELD exception score as the complications of their liver disease are similar to complications of other liver diseases and their risk of adverse events on the waiting list will be accurately predicted by the calculated MELD score. However, current guidance states that candidates with PSC meeting specific criteria can be considered for a MELD exception. The candidates must have been admitted to the intensive care unit (ICU) two or more times over a three month period for hemodynamic instability requiring vasopressors and must have cirrhosis. In addition, the candidate must have one of the following:

- Biliary tract structure that is not responsive to treatment by interventional radiology or therapeutic endoscopy
- Highly-resistant infectious organism

The intent of the current guidance is to limit MELD exceptions to only those PSC candidates with increased mortality risk and higher urgency for transplant based on the presence of advanced biliary strictures and risk of sepsis due to cholangitis.

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[25] David Goldberg et al., "Waitlist Survival of Patients with Primary Sclerosing Cholangitis in the Model for End-Stage Liver Disease Era," *Liver Transplantation* 17, no. 11 (October 26, 2011): 1355–63, https://doi.org/10.1002/lt.22396.
[26] Ibid.
[27] Further Enhancements *to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2020, Available at https://optn.transplant.hrsa.gov/
[28] All public comments are available at https://optn.transplant.hrsa.gov/

In determining if the guidance should be updated, the Committee reviewed recent data on candidates with PSC. **Table 1** shows the waitlist dropout rates per 100 patient-years waiting by PSC diagnosis and all diagnoses, stratified by MELD and PELD score.[29] Overall, the waitlist dropout rate was significantly lower for candidates with PSC, which aligns with previous research and the current guidance. However, the waitlist dropout rate was significantly higher for PSC candidates with a MELD or PELD greater than 37 or listed as status 1A or 1B.

Table 1: Liver Waitlist Dropout Rates Per 100 Patient-Years Waiting, Patients Ever Waiting During 1/01/2015 to 7/31/2020 by PSC Diagnosis and Overall

MELD or PELD Score or Status	Patient Diagnosis Group	Patients Ever Waiting	Dropouts per 100 Patient-Years	95% CI
M/P <15	All	40192	7.57	[7.29, 7.86]
	PSC	1978	3.36	[2.58, 4.31]
M/P 15-28	All	43764	19.18	[18.59, 19.78]
	PSC	2332	12.37	[10.51, 14.45]
M/P 29-32	All	16250	40.31	[37.90, 42.83]
	PSC	821	49.41	[35.75, 66.55]
M/P 33-36	All	9493	67.34	[62.56, 72.39]
	PSC	468	111.61	[71.51, 166.06]
M/P 37+, Status 1s	All	10594	339.93	[325.39, 354.94]
	PSC	387	801.61	[630.52, 1004.83]
Overall	All	66437	17.15	[16.83, 17.48]
	PSC	3083	11.20	[10.08, 12.41]

Based on this information, the Committee is proposing that the guidance for candidates with PSC be updated to recommend that candidates be admitted to the hospital two or more times within a one year period instead of recommending that candidates be admitted to the ICU two or more times over a three month period. The proposed update also states that candidates must be admitted to the hospital with a documented blood stream infection or evidence of sepsis including hemodynamic instability requiring vasopressors. The updated language is more in line with current hospital resources and may also better identify the most urgent candidates with PSC, who may be at risk of further decompensation and progression to high MELD scores with the associated increased risk of waitlist mortality compared to patients with similar high MELD scores who do not have PSC.

The Committee agreed that this proposed change will provide access to MELD exception scores for candidates with PSC before their risk of waitlist dropout increases. In addition, the Committee felt that the inclusion of ICU admissions in the guidance was subjective, as different hospitals have different thresholds for admitting patients to the ICU. The Committee is recommending the one year time period because it aligns with their effort to provide exceptions to candidates with PSC prior being too sick for transplant, while also ensuring that the hospital admissions are clinically relevant and related.[30]

The Committee is seeking public comment feedback on the proposed changes to guidance for candidates with PSC.

[29] Waitlist dropout includes removal due to death or too sick to transplant

[30] See NLRB Subcommittee meeting summary, October 8, 2020. Available at https://optn.transplant.hrsa.gov/

NOTA and Final Rule Analysis

The Committee submits the proposed changes to liver allocation policy (*Policy 9.5.A: Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions*) for Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[31] The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment**[32] because it is an evidenced-based change relying on the following evidence:
    - Medical expertise of the Committee that candidates with a hilar mass less than or equal to three centimeters in radial diameter meet the diagnostic criteria for hilar CCA.
    - Peer review literature supporting the Committee's proposal.
- **Seeks to achieve the best use of donated organs**[33] **by** ensuring organs are allocated and transplanted according to medical urgency.
    - This proposal seeks to achieve the best use of donated organs by ensuring that only those candidates meeting established clinical criteria are able to receive priority on the waitlist by being eligible for standardized CCA exceptions.
- **Is designed to…promote patient access to transplantation**[34] **by** giving similarly situated candidates equitable opportunities to receive an organ offer.
    - This proposal is designed to promote patient access to transplantation by allowing candidates meeting established clinical criteria to be eligible for a standardized CCA exception.

This proposal is not based on the candidate's place of residence or place of listing. This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[35] and it is specific to an organ type, in this case, livers.[36]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

[31] 42 CFR §121.4(a).
[32] 42 CFR §121.8(a)(1).
[33] 42 CFR §121.8(a)(2).
[34] Id.
[35] 42 CFR §121.8(a)(3).
[36] 42 CFR §121.8(a)(4).

- Shall be designed to avoid wasting organs, to avoid futile transplants, … and to promote the efficient management of organ placement;

Additionally, the OPTN issues the *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review* and *Guidance to Liver Transplant Programs and the National Liver Review Board for Pediatric MELD or PELD Exception Review* for the operation of the OPTN.[37] This guidance will support the operation of the NLRB by assisting the reviewers with evaluating exception requests. The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including "reducing inter-transplant program variance."[38] This guidance document will assist in reducing inter-transplant program variance by facilitating more consistent review of exception cases.

Implementation Considerations

Member and OPTN Operations

The proposed addition to the standardized criteria for a CCA exception in policy will need to be programmed. The changes to guidance do not need to be programmed, but all relevant guidance documents will need to be updated. All changes will be communicated to the community prior to implementation. Transplant programs and NLRB reviewers will need to be aware of the changes.

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[39] The Committee did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors.

Operations affecting Histocompatibility Laboratories

This proposal will have no operational impact on histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal will have no operational impact on organ procurement organizations.

Operations affecting Transplant Hospitals

Transplant programs will need to be familiar with the proposed changes to policy and guidance when submitting exception requests for candidates.

Operations affecting the OPTN

The proposed changes to the standardized CCA criteria will need to be programmed in UNet^{SM}. Changes to guidance will not need to be programmed but relevant guidance documents will need to be updated. The OPTN will communicate any changes prior to becoming effective and will provide educational resources as appropriate.

[37] 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.
[38] 42 C.F.R. §121.8(b)(4)
[39] 42 C.F.R. § 121.8(d).

Potential Impact on Select Patient Populations

All updates in the proposal are intended to expand the criteria for candidates to receive a MELD or PELD exception.

Candidates that meet the updated criteria for a standardized CCA exception will now be eligible to have their exception automatically approved, instead of reviewed by the NLRB. Guidance will no longer recommend that candidates with NET be less than age 60, which will likely increase the number of NET candidates who are approved for an exception. The proposed changes to PSC guidance will likely allow more candidates to receive an exception as well. Instead of requiring that candidates be admitted to the ICU two or more times in a three month period, guidance will recommend that candidates who have been admitted to the hospital two or more times in a one year period be considered for an exception. This will likely increase the number of candidates with PSC who are approved for an exception.

For pediatric candidates, the proposed changes will increase the number of candidates who are approved for an exception for growth failure or nutritional insufficiency, ascites requiring a hospitalization, or rare metabolic diseases. The additional changes to guidance provide more specificity on the information that should be provided by transplant programs when applying for exceptions, which does not expand the guidance, but does increase the likelihood of having an exception approved.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

This proposal is not expected to have a fiscal impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

This proposal is not expected to have a fiscal impact on organ procurement organizations.

Projected Impact on Transplant Hospitals

This proposal is not expected to have a fiscal impact on transplant hospitals.

Projected Impact on the OPTN

The proposal is a demand-sized programming requested, requiring an estimated 150 hours to program. Additional implementation and ongoing support is estimated to be 180 hours.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”[40]

[40] 42 CFR §121.8(a)(7).

The proposed language will not change the current routine monitoring of OPTN members. Site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation including all qualifying criteria used for standardized exceptions reported on the MELD or PELD exception or exception extension form.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[41] In addition to those monitoring reports and items previously enumerated in post-implementation evaluation plans related to the NLRB, the UNOS Research Department will analyze relevant outputs in pre vs. post analyses for the additional policy changes and guidance updates. Such analyses will continue the cadence of previously laid out evaluation plans for the NLRB, or longer if requested by the Committee.

Relevant analyses:

- Number and percent of pediatric exception requests
    - Overall and by case outcome
- Number and percent of CCA exceptions meeting standard policy criteria versus requiring review by NLRB
- Number of exception cases for NET
    - Overall and by case outcome
- Number of exception cases for PSC/SSC
    - Overall and by case outcome

Additional metrics as requested by the Committee, relevant to the proposed policy and guidance changes.

Conclusion

This proposal represents the most recent effort of the Committee to continuously improve the NLRB based on published research and feedback from the transplant community. The proposed updates to the standardized criteria for CCA will ensure that the appropriate candidates are eligible to have their exception automatically approved. The proposed changes to pediatric guidance reflect feedback from the pediatric community and include updates to guidance for growth failure/nutritional insufficiency, complications of portal hypertension including ascites and gastrointestinal bleeding, and the conclusion. The proposal also adds a new section for candidates with rare metabolic disorders. The proposed changes to NET guidance will recommend candidates over the age of 60 be considered for a MELD exception. Additionally, the proposed updates to guidance for candidates with PSC will provide a pathway for candidates to receive a MELD exception prior to becoming too sick for transplant. Together, these proposed changes will improve the NLRB and the overall liver allocation system.

[41] 42 CFR §121.8(a)(6).

Policy and Guidance Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for CCA, if the candidate's transplant hospital meets *all* the following qualifications:

1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include *all* of the following:
   - Candidate selection criteria
   - Administration of neoadjuvant therapy before transplantation
   - Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   - Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and at least *one* of the following:
   - Biopsy or cytology results demonstrating malignancy
   - Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
   - Aneuploidy
   - <u>Hilar mass, which is less than or equal to 3 cm in radial diameter (if not less than or equal to 3 cm in radial diameter, or extension into liver parenchyma, the mass exceeds size criteria and the candidate is not eligible for a standardized exception)</u>

   The tumor must be considered un-resectable because of technical considerations or underlying liver disease.

3. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a mass, the mass must be single and less than three cm.

4. Documents the exclusion of intrahepatic and extrahepatic metastases by cross-sectional imaging studies of the chest and abdomen within 90 days prior to submission of the initial exception request.

5. Assesses regional hepatic lymph node involvement and peritoneal metastases by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.

6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) must be avoided because of the high risk of tumor seeding associated with these procedures.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-2*.

Table 9-2: CCA Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Exception Extensions,* and provide cross-sectional imaging studies of the chest and abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging studies must have been completed within 30 days prior to the submission of the extension request.

Guidance to Liver Transplant Programs and the National Liver Review Board for:

Pediatric MELD/PELD Exception Review

Growth Failure or Nutritional Insufficiency

~~There is insufficient evidence to support approval of exception points for pediatric candidates with any broadly defined growth failure or nutritional insufficiency. However,~~ It is now known that the PELD score, as currently calculated, does not accurately capture growth failure for all children. ~~e~~Exceptions should be considered for candidates who meet any of the following criteria:

- Growth parameters
  - ~~For candidates over 1 year of age,~~ < 5th percentile for: height, weight (may adjust to estimated dry weight if ascites)
  - Z-score ~~(Weight for height)~~ (weight, height, or BMI/weight-for-length) less than 2 standard deviations below the mean for age and gender
- Anthropometrics
  - Triceps s~~S~~kin fold thickness or mid-arm muscle circumference < 5th percentile for age and gender ~~for children > 1 year~~
- Failure of nasoenteric tube feedings as evidenced by failure to demonstrate improvement in growth failure in the previous month based on either weight or anthropometrics
- Requirement for TPN nutrition to allow for growth or to maintain euglycemia

Complications of portal hypertension, including ascites and gastrointestinal bleeding

Approval of MELD or PELD exception points for hospitalized pediatric candidates with complications of portal hypertension may be appropriate in some instances. Documentation submitted for case review should indicate:

- Gastrointestinal bleeding with on-going transfusion requirement, specification of interventions and treatments attempted or contraindications to their use, and the amount and dates of transfusions
- ~~Transjugular intrahepatic portosystemic shunt (TIPS) placement as a bridge to transplant. Indicate if TIPS is not an option or variceal bleeding unresponsive to ablative therapy~~
- ~~Ongoing octreotide administration~~

There is insufficient evidence to support approval of exception points in the presence of splenomegaly or varices without bleeding. There is also insufficient evidence to support approval of exception points for pediatric candidates with ascites controlled by diuretics in the outpatient setting. Exception points may be considered for candidates with severe or complicated ascites in at least one of the following clinical scenarios:

- Serum sodium less than 130, two times greater than 2 weeks apart (specify dates, values, and treatment required to demonstrate persistence and severity)

- Multiple therapeutic paracenteses (at least 2 in the previous 30 days, not including diagnostic paracentesis)
- Hydrothorax requiring chest tube or therapeutic thoracentesis (at least 2 in the previous 60 days, not including diagnostic thoracentesis)
- Patients requiring a hospitalization of at least 5 days with ascites not adequately controlled by oral diuretics and requiring IV diuretic therapy

Metabolic Liver Disease

In addition to the standard metabolic indications for transplant, there are rare metabolic diseases that present in childhood with liver failure, cirrhosis, or other life-threatening complications that may be successfully ameliorated by liver transplant. An exhaustive list of rare disorders that could be appropriate for a MELD or PELD exception is beyond the scope of this guideline. Approval of MELD or PELD exceptions may be appropriate in cases of rare metabolic disease in which liver transplant can ameliorate the life-threatening risk of the disease.

Transplant programs should submit:

- How liver transplant addresses disease complications and mortality risk
- Reference to other comparable MELD or PELD exception categories as appropriate, to justify points requested
- Experience from other cases in which liver transplant was utilized, from published literature or other.

Conclusion

Liver transplant programs, Review Board members and the Committee should consult this resource when assessing pediatric MELD, PELD and status exception requests. Liver programs should also consider this guidance when submitting exception requests for pediatric candidates with these diagnoses. However, these guidelines are not prescriptive of clinical practice.

This guidance may not be reflective of all available evidence pertinent to a specific case. Additional evidence pertinent to a child's clinical course can also be considered when reviewing exception applications.

Guidance to Liver Transplant Programs and the National Liver Review Board for:

Adult MELD Exception Review

Neuroendocrine Tumors (NET)

A review of the literature supports that candidates with NET are expected to have a low risk of waiting list drop-out. ~~Initial recommendations included age less than 60. Older patients with a lot of disease burden may be referred to transplant as a last resort, leading to poor outcomes, while data presented at the AASLD show that very young patients with NET and early stage disease do well. Committee members believed that these initial guidelines could include strict criteria that could be expanded based upon the experience of the Review Board.~~

Transplant programs should ~~also~~ be aware of ~~these~~ the following criteria when submitting exceptions for NET. The Review Board should consider the following criteria when reviewing exception applications for candidates with NET.

- ~~Recipient age <60 years.~~
- Resection of primary malignancy and extra-hepatic disease without any evidence of recurrence at least six months prior to MELD exception request.
- Neuroendocrine Liver Metastasis (NLM) limited to the liver, Bi-lobar, not amenable to resection.

Tumors in the liver should meet the following radiographic characteristics on *either* CT or MRI:

1. If CT Scan:
    a. Triple phase contrast Lesions may be seen on only one of the three phases
    b. Arterial phase: may demonstrate a strong enhancement
    c. Large lesions can become necrotic/calcified
2. If MRI Appearance:
    a. Liver metastasis are hypodense on T1 and hypervascular in T2 wave images
    b. Diffusion restriction
    c. Majority of lesions are hypervascular on arterial phase with wash –out during portal venous phase
    d. Hepatobiliary phase post Gadoxetate Disodium (Eovist): Hypointense lesions are characteristics of NET

1. Consider for exception only those with a NET of Gastro-entero-pancreatic (GEP) origin tumors with portal system drainage. Note: Neuroendocrine tumors with the primary located in the lower rectum, esophagus, lung, adrenal gland and thyroid are not candidates for automatic MELD exception.
2. Lower - intermediate grade following the WHO classification. Only well differentiated (Low grade, G1) and moderately differentiated (intermediate grade G2). Mitotic rate <20 per 10 HPF with less than 20% ki 67 positive markers.
3. Tumor metastatic replacement should not exceed 50% of the total liver volume.
4. Negative metastatic workup should include one of the following:

a. Positron emission tomography (PET scan)
b. Somatostatin receptor scintigraphy
c. Gallium-68 (68Ga) labeled somatostatin analogue 1,4,7,10-tetraazacyclododedcane-N, N', N",N'"-tetraacetic acid (DOTA)-D-Phe1-Try3–octreotide (DOTATOC), or other scintigraphy to rule out extra-hepatic disease, especially bone metastasis.

Note: Exploratory laparotomy and or laparoscopy is not required prior to MELD exception request.

1. No evidence for extra-hepatic tumor recurrence based on metastatic radiologic workup at least 3 months prior to MELD exception request (submit date).
2. Recheck metastatic workup every 3 months for MELD exception increase consideration by the Review Board. Occurrence of extra-hepatic progression – for instance lymph-nodal Ga68 positive locations – should indicate de-listing. Patients may come back to the list if any extra-hepatic disease is zeroed and remained so for at least 6 months.
3. Presence of extra-hepatic solid organ metastases (i.e. lungs, bones) should be a permanent exclusion criteria

Primary Sclerosing Cholangitis or Secondary Sclerosing Cholangitis

Candidates with Primary Sclerosing Cholangitis (PSC) or Secondary Sclerosing Cholangitis (SSC) ~~historically have low mortality rates, and therefore do not need exception scores.~~ may be at risk of adverse outcomes secondary to sepsis from cholangitis, which may not be reflected in the candidate's calculated MELD score. Based on clinical experience and a review of the available literature, the Committee recommends that ~~four specific~~ the following elements be considered.

~~**Transplant programs should provide the following criteria when submitting exceptions for PSC or SSC. The Review Board should consider the following criteria when reviewing exception applications for candidates with PSC or SSC.**~~

The candidate must meet both of the following two criteria:

1. The candidate has been admitted ~~to the intensive care unit (ICU)~~ to the hospital two or more times ~~over a three month period for hemodynamic instability requiring vasopressors~~ within a one year period with a documented blood stream infection or evidence of sepsis including hemodynamic instability requiring vasopressors
2. The candidate has cirrhosis

In addition the candidate must have one of the following criteria:

- The candidate has biliary tract stricture which are not responsive to treatment by interventional radiology (PTC) or therapeutic endoscopy (ERCP) or
- The candidate has been diagnosed with a highly-resistant infectious organism (e.g. Vancomycin Resistant Enterococcus (VRE), Extended Spectrum Beta-Lactamase (ESBL) producing gram negative organisms, Carbapenem-resistant Enterobacteriaceae (CRE), and Multidrug-resistant Acinetobacter.)

Appendix 1: PSC Data

The Committee reviewed the following data when discussing the proposed changes to PSC guidance.

Figure 1: Number of Registrations on Liver Waiting List with PSC Diagnosis during 1/1/2018-7/31/2020, by Month

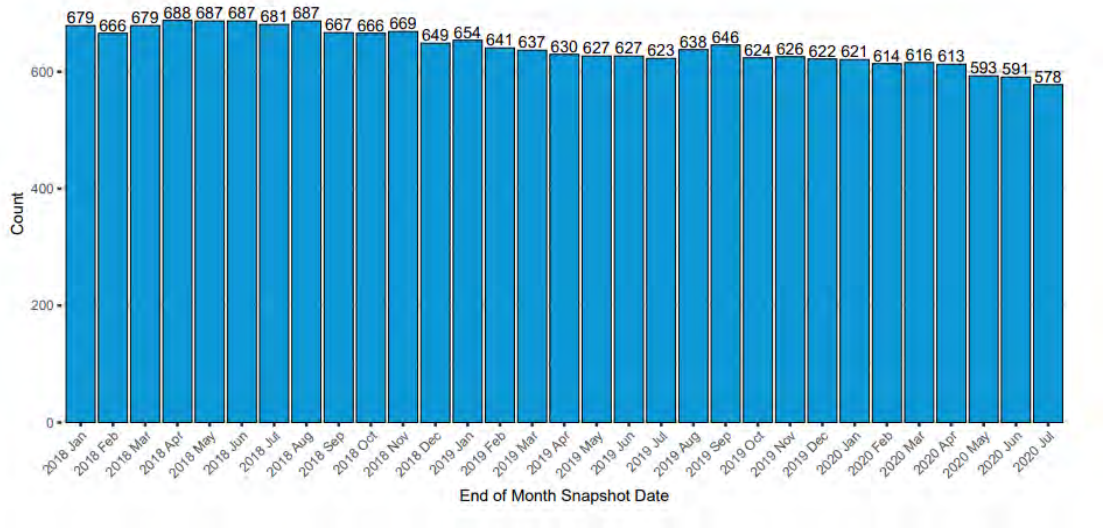

Figure 2: Percent of Registrations on Liver Waiting List with PSC Diagnoses during 1/1/2018 - 7/31/2020 by Month

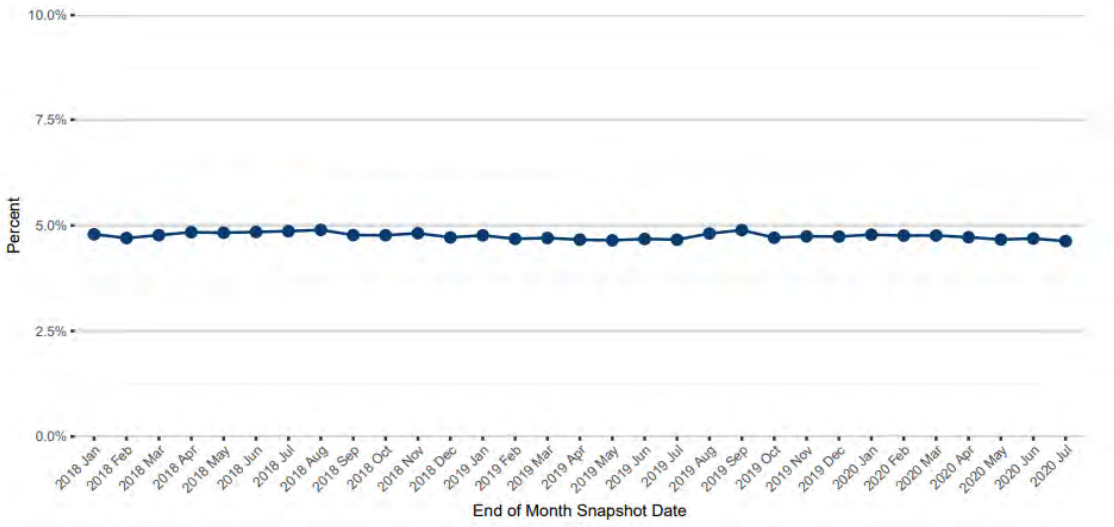

Figure 3: Liver Waiting List Drop-Out Rates per 100 Patient-Years Waiting, Patients Ever Waiting During 1/1/2015 - 7/31/2020, by PSC Diagnosis and Overall

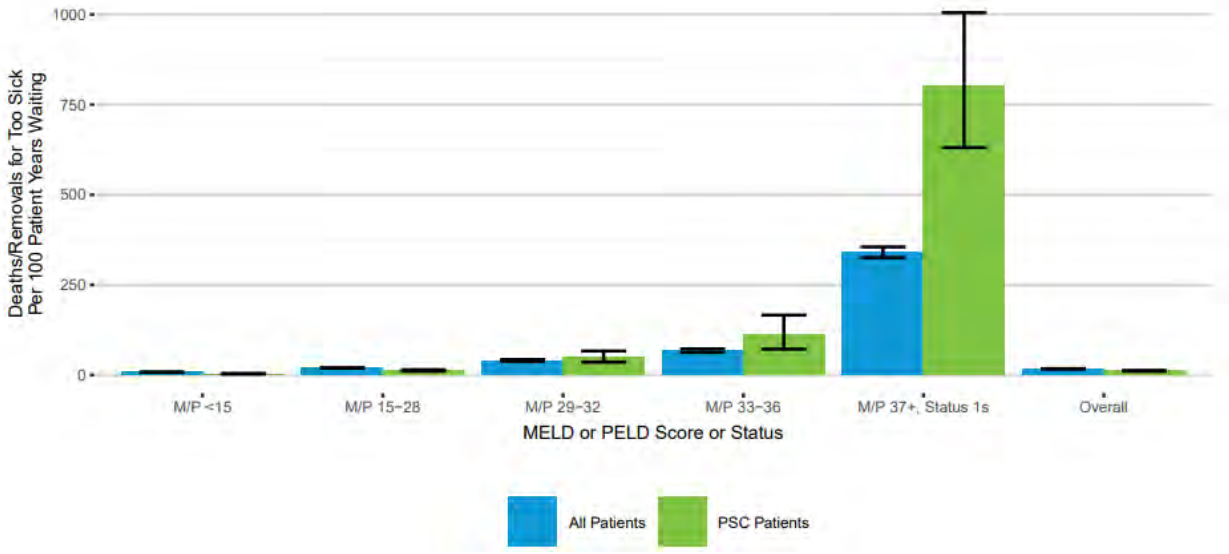

Table 2: Liver Waitlist Dropout Rates Per 100 Patient-Years Waiting, Patients Ever Waiting During 1/01/2015 to 7/31/2020 by PSC Diagnosis and Overall

MELD or PELD Score or Status	Patient Diagnosis Group	Patients Ever Waiting	Dropouts per 100 Patient-Years	95% CI
M/P <15	All	40192	7.57	[7.29, 7.86]
	PSC	1978	3.36	[2.58, 4.31]
M/P 15-28	All	43764	19.18	[18.59, 19.78]
	PSC	2332	12.37	[10.51, 14.45]
M/P 29-32	All	16250	40.31	[37.90, 42.83]
	PSC	821	49.41	[35.75, 66.55]
M/P 33-36	All	9493	67.34	[62.56, 72.39]
	PSC	468	111.61	[71.51, 166.06]
M/P 37+, Status 1s	All	10594	339.93	[325.39, 354.94]
	PSC	387	801.61	[630.52, 1004.83]
Overall	All	66437	17.15	[16.83, 17.48]
	PSC	3083	11.20	[10.08, 12.41]

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Figure 4: Number of Deceased Donor, Liver-Alone Transplant Recipients with PSC Diagnosis during 1/1/2018-7/3/2020

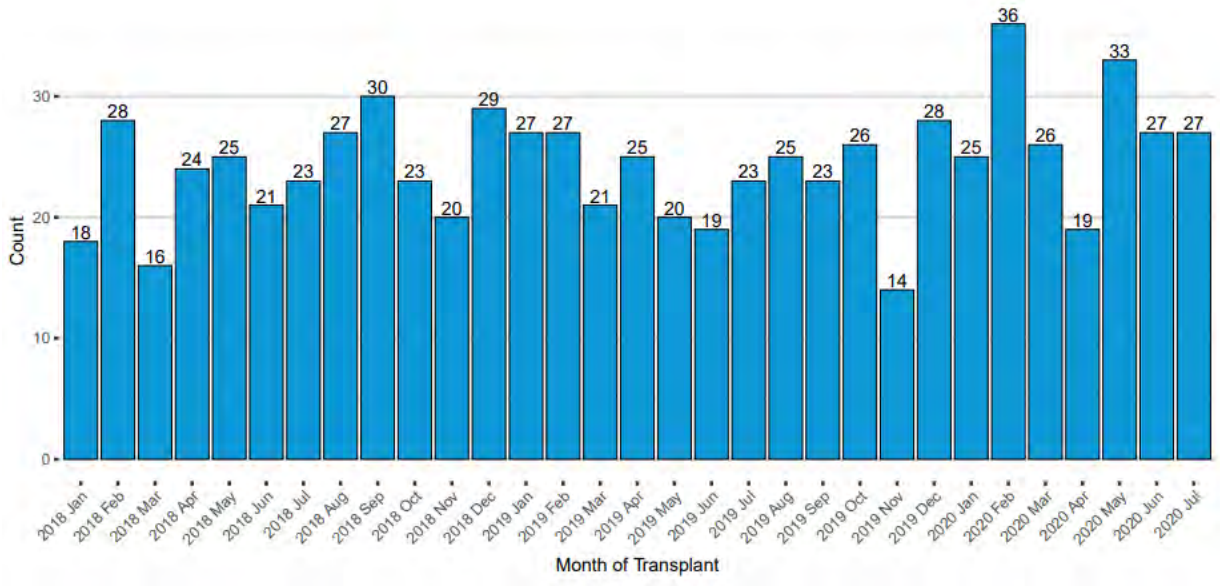

Figure 5: Percent of Deceased Donor, Liver-Alone Transplant Recipients with PSC Diagnosis during 1/1/2015 - 7/31/2020, by Month

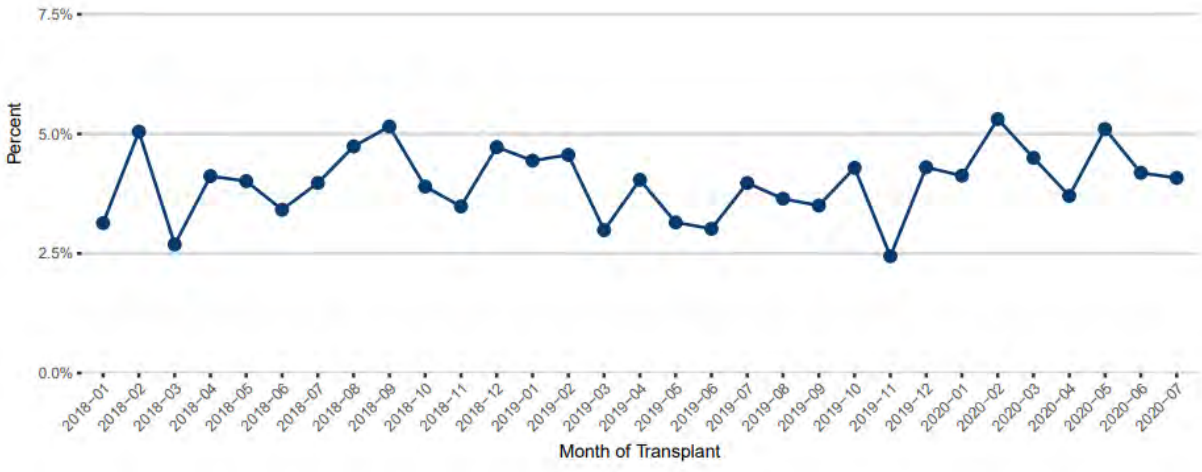

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Figure 6: Liver Transplant Rates per 100 Patient-Years Waiting, Patients Ever Waiting during 1/1/2015 - 7/31/2020, by PSC Diagnosis and Overall

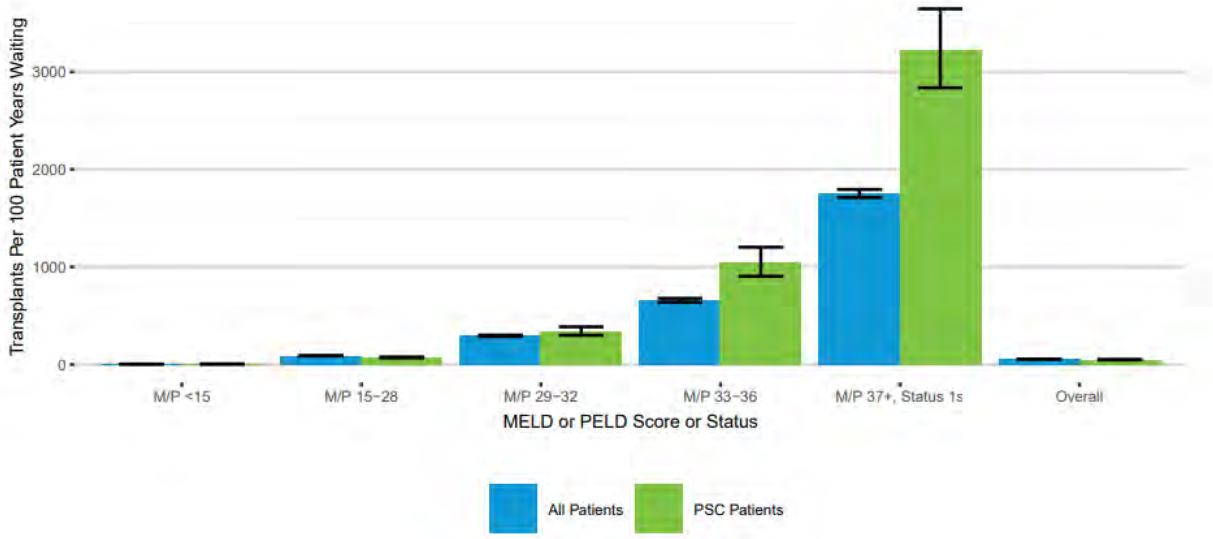

Table 3: Liver Transplant Rates per 100 Patient-Years Waiting, Patients Ever Waiting during 1/1/2015-7/31/2020, by PSC Diagnosis and Overall

MELD or PELD Score or Status	Diagnosis Group	Patients Ever Waiting	Transplants per 100 Patient-Years	95% CI
M/P <15	All	38876	4.70	[4.46, 4.96]
	PSC	1931	5.09	[4.03, 6.34]
M/P 15-28	All	43165	89.85	[88.44, 91.27]
	PSC	2317	73.00	[68.12, 78.14]
M/P 29-32	All	16136	294.09	[286.49, 301.84]
	PSC	819	341.35	[300.35, 386.39]
M/P 33-36	All	9427	658.14	[638.17, 678.57]
	PSC	466	1044.69	[903.20, 1202.06]
M/P 37+, Status 1s	All	10534	1752.77	[1712.44, 1793.80]
	PSC	386	3220.59	[2835.19, 3643.75]
Overall	All	66437	54.52	[53.94, 55.11]
	PSC	3083	49.28	[46.90, 51.75]

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Appendix 2: NET Data

In addition to the data included in the proposal, the Committee also considered the following data when discussing the proposed changes to NET guidance.

Table 4: NET Post-Transplant Patient and Graft Survival

Organ Procurement and Transplantation Network
Kaplan-Meier 1,3,5 Year Patient and Graft Survival Rates for Liver Transplants Performed in US January 01, 2000-July 31, 2015
Where Recipient Diagnosis 'Other text' or Exception Diagnosis 'Other text' had Neuroendocrine Tumor or Carcinoid
Note: Repeat and Multi-Organ transplants excluded
Note: '*' denotes values couldn't be calculated because n at risk was less than or equal to 10

Recipient Age Group at Transplant	Transplants Performed N	1 Year Post Transplant		3 Year Post Transplant		5 Year Post Transplant	
		Patient Survival Rate [95% CI]	Graft Survival Rate [95% CI]	Patient Survival Rate [95% CI]	Graft Survival Rate [95% CI]	Patient Survival Rate [95% CI]	Graft Survival Rate [95% CI]
11-17	7	*	*	*	*	*	*
18-34	21	90.48 [67.00, 97.53]	90.48 [67.00, 97.53]	80.95 [56.89, 92.39]	80.95 [56.89, 92.39]	80.95 [56.89, 92.39]	80.95 [56.89, 92.39]
35-49	50	80.89 [66.46, 89.57]	74.00 [59.47, 83.99]	69.96 [54.57, 80.99]	64.00 [49.11, 75.57]	63.40 [47.86, 75.44]	58.00 [43.18, 70.24]
50-64	73	88.22 [77.80, 93.93]	80.64 [69.50, 88.05]	68.78 [56.23, 78.40]	63.95 [51.75, 73.84]	59.63 [46.87, 70.27]	55.45 [43.23, 66.05]
65+	10	*	*	*	*	*	*
Overall	161	86.28 [79.73, 90.84]	79.43 [72.31, 84.91]	69.56 [61.53, 76.24]	65.04 [57.12, 71.87]	62.05 [53.76, 69.28]	58.02 [49.96, 65.24]

Based on OPTN data as of September 04, 2020
Data subject to change based on future data submission or correction

OPTN

Request for Feedback

Update Transplant Program Key Personnel Training and Experience Requirements

OPTN Membership and Professional Standards Committee

Prepared by: Sharon Shepherd
UNOS Member Quality

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Update Transplant Program Key Personnel Training and Experience Requirements

Sponsoring Committee: *Membership and Professional Standards Committee*
Public Comment Period: *January 21, 2021 – March 23, 2021*

Executive Summary

The National Organ Transplant Act (NOTA) and the Final Rule require that the Organ Procurement and Transplantation Network (OPTN) establish membership requirements. The current OPTN contract with the Health Resources and Services Administration (HRSA) requires the creation of a new process for periodically reassessing members' compliance with these OPTN membership requirements, including changes to the OPTN bylaws necessary for the effectiveness of the reassessment process. As there had not been a comprehensive review of all OPTN membership requirement bylaws since the mid-2000s, the OPTN Membership and Professional Standards Committee (MPSC) began a phased project to review all membership requirements. The project goals included ensuring the requirements support a process for periodic evaluation of member compliance with OPTN bylaws, evaluating the requirements' consistency with NOTA, federal regulations and current practice and qualifications, and reducing complexity of the requirements to simplify the application process and the review of applications by the OPTN.

The MPSC has reviewed and is considering changes to the format used to develop transplant program key personnel training and experience requirements. The majority of the organ-specific training and experience requirements for key personnel, primary transplant surgeons and primary transplant physicians, contain the same requirements which have been modified to include organ-specific details. The MPSC is requesting feedback on suggested changes to this format prior to collaborating with OPTN organ-specific committees to apply these changes to the organ-specific training and experience bylaws.

Purpose

The current OPTN contract with HRSA requires the creation of a process for periodically reassessing members' status in the OPTN, including changes to the bylaws necessary for the effectiveness of the reassessment process. As there had not been a comprehensive review of all OPTN membership requirement bylaws since the mid-2000s, the Membership and Professional Standards Committee (MPSC) began a phased project to review all membership requirements to ensure the requirements will support a process for periodic evaluation of member compliance with OPTN bylaws; to evaluate the requirements for consistency with NOTA, federal regulations and current practice and qualifications; and to reduce complexity of the requirements to simplify the application process and the review of applications by the OPTN.

The MPSC has examined the transplant program primary surgeon and primary physician training and experience requirements based on issues that have arisen in reviews of applications, feedback received from members completing applications for new programs and key personnel changes, and the ability to apply a periodic reassessment of compliance. Based on this review, the MPSC is considering a revised format that can be used for the development of updated training and experience requirements for primary surgeons and physicians. The MPSC is requesting feedback on the format first and will then collaborate with the OPTN organ-specific committees to apply the format to the applicable primary surgeon and primary physician training and experience requirements in OPTN Bylaws, Appendices E through K.

Background

The OPTN Final Rule requires that the OPTN develop policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs,[1] and requires that designated transplant programs have on site a transplant surgeon and transplant physician who is qualified under the policies developed.[2] Pursuant to the Final Rule requirements, the OPTN has developed training and experience bylaw requirements for primary surgeons and primary physicians for each designated organ transplant program.[3] The OPTN bylaws also contain a requirement for a program coverage plan and defines the qualifications for additional transplant surgeons and additional transplant physicians that can provide coverage, in addition to the primary surgeons and physicians.[4]

The primary transplant surgeon and primary transplant physician are the surgical and medical leaders of a designated transplant program and are generally responsible for ensuring the operation and compliance of the program with OPTN obligations.[5] To promote public health and patient safety in the transplant community, the OPTN bylaws provide the minimum requirements for a transplant surgeon to serve as the primary transplant surgeon and for a transplant physician to serve as the primary transplant physician.[3] Providing specific, detailed, and easily understood requirements for primary transplant surgeons and physicians helps ensure consistency and transparency, and assists members by providing information necessary for a program to assess whether an individual that will potentially be hired to fill the primary role meets the necessary requirements.

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[1] 42 C.F.R. §121.4(a)(4)

[2] *Id.* at §121.9(a)(2)(ii)-(iii)

[3] OPTN Bylaws, Appendices E – J.

[4] OPTN Bylaws, Appendix D, D.7.B.

[5] OPTN Bylaws, Appendix D, D.7.A.

As the MPSC embarked on a review of the primary surgeon and primary physician training and experience requirements, the Committee endorsed a number of principles to guide the review. The principles support the implementation of a process for periodic reassessment of compliance as required by the OPTN contract, simplification of the training and experience requirements, and flexibility for qualified individuals with varying training and experience background. These overarching principles include:

- Incorporating an element of currency, or recency, into the experience requirements
- Consolidating the multiple training and experience pathways into one pathway that can be met through fellowship experience and clinical experience or a combination of both
- Ensuring consistency between all organ-specific training and experience requirements, where possible
- Considering stratification of requirements that would expect only individuals who had not previously served in the position of primary surgeon or physician to meet certain requirements
- Incorporating an option for individuals who trained or gained experience outside of the United States to qualify as a primary surgeon or physician that would be consistent with and equivalent to the requirements for those who trained or gained experience within the United States.

During its evaluation of the primary surgeon and primary physician bylaw requirements, the MPSC evaluated feedback received from members who have submitted key personnel applications, and issues the MPSC has identified during the review of applications. The MPSC consulted state licensing requirements, requirements for various board certifications, fellowship requirements and past briefing papers supporting existing bylaws.

Currency

The current transplant program key personnel bylaws contain limited requirements regarding a proposed individual's current transplantation experience. The sole requirement is for a proposed primary to demonstrate direct involvement in transplantation in the last two years, meaning a surgeon performed at least one transplant and a physician cared for at least one transplant recipient in the last two years. Otherwise, a surgeon or physician can rely on clinical experience gained during any two to five year period or during a fellowship completed many years ago. For example, under the current bylaws, a proposed individual can be approved for a primary position provided they have performed just one transplant or cared for just one transplant recipient in the last two years, even if the proposed primary otherwise has not been involved in transplantation for 20 years.

To address this issue, the MPSC proposes requiring any experience used to meet the primary surgeon and primary physician requirements be within a certain recent time frame. For example, the bylaws may require the surgeon to have performed X number of transplants within the last 5 years. Requiring documentation of recent experience ensures that the primary surgeon or physician has remained involved in transplantation and maintained knowledge of current practice and OPTN obligations and the necessary skill set in the rapidly changing field of transplantation.

In addition, this proposed change supports the establishment of a periodic assessment of compliance with membership requirements as required by the OPTN contract. Under the current bylaws, a transplant program need only submit documentation for a qualified primary surgeon or physician when there is a change in the individual holding that position. The MPSC has encountered situations, through other monitoring activities, where the individual serving in a primary role is no longer actively involved in transplant or clearly would not meet the current training and experience bylaws for primary surgeons

or physicians. The addition of a reassessment of compliance with membership requirement bylaws will ensure that primary surgeons and physicians have remained involved in transplantation and maintained knowledge of current practice.

Consolidation of Training and Experience Pathways

The MPSC supports simplifying the requirements through consolidation of multiple pathways into one comprehensive pathway, where possible. Many of the current organ-specific key personnel bylaws contain multiple complex pathways. A single pathway would allow the use of fellowship and clinical experience to meet the specific experience requirements. This concept was successfully applied in the recently implemented intestine transplant key personnel requirements. Without acceptance of combined fellowship and clinical experience through a consolidated single pathway, the MPSC's implementation of the currency requirement, discussed in the previous paragraph, could result in increased rejection of key personnel applications when a proposed individual's most recent experience includes both time during fellowship and post-fellowship experience.

Consistency

The MPSC has developed the proposed revised format to promote consistency in language between all organ-specific primary surgeon and physician training and experience bylaws. Although all of the organ-specific key personnel requirements follow the same general format, revisions have been made to individual organ-specific requirements over the years. These changes have resulted in inconsistencies in language that are unrelated to a unique organ-specific training or experience characteristic and add complexity and confusion to the application completion and review process. Establishing a consistent format with consistent language for all organ-specific key personnel requirements will reduce the burden on member applicants and on the MPSC members reviewing the application.

Stratification of Select Key Personnel Requirements

The MPSC examined common barriers experienced by transplant programs completing key personnel applications. One of the most common issues is the inability of senior clinicians with significant experience to produce documentation for some aspects of their experience that they may have gained early in their career or during their fellowship but no longer routinely perform as a senior clinician, such as procurements for surgeons or observations of transplants and procurements for physicians. Currently, all individuals proposed for primary surgeon and physician positions are required to meet all of the training and experience requirements regardless of previous experience in the role of primary surgeon or physician.

The MPSC proposes stratifying requirements so proposed primary surgeons and physicians who have not previously served in a primary role within a certain time period would be required to provide documentation of all experience requirements. Conversely, individuals who have served as a primary physician or surgeon would not need to provide documentation of certain experience. This stratification will ensure that all primary surgeons and physicians have completed the requirement at least once in their career, but will not require seasoned clinicians to maintain recency in that area or repeatedly submit documentation about their experience. The MPSC proposes that the stratification exempt individuals from certain requirements if the individual has served as a primary physician or surgeon within the last 10 years. The MPSC is interested in feedback about this time frame, specifically whether the time frame is too restrictive or too lenient.

Options for Individuals Who Trained or Gained Experience outside the U.S.
The MPSC is committed to providing options and opportunities for qualified individuals who trained or gained transplant experience outside the United States. However, the MPSC has struggled to clearly define what training or experience would demonstrate equivalency in a way that satisfactorily provides transparency to members and supports consistency in decision-making by the MPSC. Issues of foreign equivalency arise most often in the context of board certification requirements and documentation of experience. The MPSC has identified foreign equivalency as an area about which the committee would appreciate significant input from the community. Additional specific information on the MPSC discussions, the alternatives considered, and specific questions are addressed in a separate section on foreign equivalency.

Potential Transplant Program Key Personnel Format

The proposed new transplant program key personnel bylaw format can be found in Attachment A to this Request for Feedback. For comparison purposes, please review the current OPTN Bylaws on the OPTN website at https://optn.transplant.hrsa.gov/governance/bylaws/. Again, the MPSC plans to utilize the format, once it is complete, with the organ-specific OPTN committees to finalize proposed changes to the organ-specific key personnel requirements. The MPSC will then submit the changes for public comment.

In this section, each of the proposed elements of the new transplant program key personnel bylaw format will be addressed, including a summary of the discussion and the basis for the MPSC recommendation. The section is divided into four subsections:

- Subsection 1: Requirements that appear in both the primary surgeon and primary physician requirements
- Subsection 2: Primary surgeon requirements
- Subsection 3: Primary physician requirements
- Subsection 4: Foreign equivalency

Requirements that appear in both primary transplant surgeon and primary transplant physician requirements

Certain requirements are common to both primary surgeons and primary physicians. The MPSC proposes keeping many of these requirements but has made some adjustments to simplify and clarify the requirements. The MPSC's recommendations are based on feedback from the community, MPSC reviewers, and UNOS staff who process key personnel applications. The MPSC proposes the following requirements apply to both surgeons and physicians:

1. The [surgeon][physician] must
    a. Have an M.D., D.O., or equivalent degree from another country
    b. Have a current license to practice medicine in the hospital's state or jurisdiction
    c. Be accepted and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
    d. Be on site at this hospital.
2. The [surgeon][physician] must have current certification by [list of boards].
3. An OPTN form that certifies that the [surgeon][physician] meets the requirements for a [ORGAN] primary [surgeon][physician], is qualified to lead a [ORGAN] transplant program, is

a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary [surgeon][physician], fellowship director, division chief, or department chair from the program where the [surgeon][physician]'s experience or training was gained must be submitted.

4. The [surgeon] [physician] must provide a letter that details the training and experience the [surgeon][physician] has gained in [ORGAN] transplantation.
5. If the proposed [surgeon][physician] has not served as a primary transplant [surgeon][physician] at an OPTN designated transplant program within the last 10 years, the [surgeon][physician] must have completed the OPTN orientation curriculum for primary transplant [surgeons][physicians].

In addition to the above list, the MPSC is also proposing extending the existing primary physician conditional program pathways to surgeons. Each of these proposed requirements is addressed in detail in the discussion below.

The first element requires that the surgeon or physician have an appropriate medical degree including a M.D., D.O. or equivalent degree from another country, have a current medical license in the hospital's state or jurisdiction, be a member in good standing on the hospital's medical staff and be on site. These requirements are all included in the current bylaws. The MPSC considers these to be essential basic qualifications and proposes their retention.

On-site

The MPSC had substantial discussions on the requirement for the primary surgeon and primary physician to be "on site." The OPTN Final Rule §121.9 requires that "an organ transplant program . . . has on site a transplant surgeon qualified in accordance with policies developed under §121.4 [and] has on site a transplant physician qualified in accordance with policies developed under §121.4." The Final Rule §121.4 requires the development of "[p]olicies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by §121.9." Current bylaws require that the transplant program must have key personnel, meaning a primary surgeon and primary physician, "on site" at the hospital. The Final Rule requirement for a transplant surgeon and transplant physician to be on site has been met by the separate OPTN bylaw requirement for a program coverage plan. The program coverage plan requires that a transplant surgeon and transplant physician, either the primary surgeon or physician or an additional surgeon or physician as defined in OPTN bylaws, provide continuous medical and surgical coverage. Programs that do not have any additional surgeons or physicians, and therefore only have coverage by the single primary surgeon or physician, are required to notify patients of the potential unavailability of these individuals which could affect patient care including the ability to accept organ offers, procurement and transplantation. See the requirements for the program coverage plan in Appendix D: *Transplant Hospital Members and Designated Transplant Programs*.

The separate requirement for primary surgeons and primary physicians to be on site at the hospital as noted in item 1.d above is admittedly difficult to operationalize. The OPTN has not expected or required a primary surgeon or physician be at the hospital continuously or even be continuously available to the hospital. Instead, the requirement has been applied to require that the primary surgeon and physician be physically available to provide leadership to the program, actively participate in the provision of transplant services, and ensure the operation of the program is in compliance with OPTN obligations. The MPSC has rejected an application that proposed that an individual serve as the primary for one program while also simultaneously serving a program several states away. Conversely, the MPSC has

approved applications when the proposed primary will serve as primary for two separate programs, if the programs are located in the same geographical area. In these cases, the MPSC has evaluated the ability of the individual to fulfill the primary duties in light of the distance between programs, the programs' transplant volumes, the availability of additional surgeons or physicians, and other relevant factors. The MPSC has struggled to determine language that reflects the availability and commitment of a program's primary surgeon and physician that would provide the necessary level of guidance to members and flexibility to the MPSC in evaluating the unique circumstances of a program, while not inadvertently creating an additional requirement, above the requirements of the Final Rule, that the *primary* physician and surgeon must always be on site in addition to any other physicians and surgeons who are also qualified in accordance with policies developed by the OPTN under §121.4 of the Final Rule. At this time, however, the MPSC supports the continued use of the term "on site" in the primary surgeon and physician requirements and will continue to evaluate compliance with this requirement based on historical precedent as described above. The MPSC requests feedback from the community on this requirement in order to further evaluate the appropriate responsibilities and expectations for primary surgeons and physicians in a separate future project focused solely on this requirement. Keeping in mind that the primary surgeon and physician are the surgical and medical leaders of a transplant program and are responsible for ensuring the program remains in compliance with OPTN obligations, the MPSC is requesting feedback on the following questions:

- What should be the responsibilities of the primary surgeon and primary physician?
- What level of commitment to a transplant program must a surgeon and physician demonstrate to fulfill the role of primary surgeon and primary physician?

Board Certification

The second element requires appropriate American or Canadian board certification and is a current requirement in the bylaws. The MPSC has reviewed applications proposing individuals who trained outside the United States or Canada, and are therefore, ineligible for American or Canadian board certification, but otherwise appear imminently qualified. In response to a strongly held position that there must be a reasonable pathway for surgeons and physicians trained outside the United States to serve as primaries, the MPSC considered the option of eliminating the requirement for board certification. During the MPSC discussions on this topic, some committee members noted that board certification is unrelated to transplant and suggested requiring transplant fellowships instead of board certifications. The MPSC noted that transplant fellowships are not mandatory, and felt that relying on fellowships would actually exclude qualified individuals from serving in a primary role. The majority of MPSC members noted that the OPTN has a responsibility to patients to ensure that surgeons and physicians are qualified and felt that board certification for American and Canadian trained individuals is a minimum qualification requirement that serves as a base threshold for competence. Maintaining board certification requires the individual to participate in continuing medical education and maintain knowledge of current practice. Accordingly, the MPSC proposes to retain the requirement for certification and maintenance of board certification from an appropriate American or Canadian surgical or physician certifying organization. A list of the current accepted board certifications for each organ can be found in Attachment B. The MPSC recognizes that individuals who train outside of the United States or Canada will be unable to meet this requirement and have addressed this issue in the Foreign Equivalency section below.

Letters of reference and recommendation

The third element replaces the current bylaw requirements for two separate letters – a letter of reference and a letter of recommendation – with a single OPTN form certifying that the proposed individual meets the requirements for a primary, is qualified to lead a transplant program, is a person of

honesty and integrity, and has experience in adhering to OPTN obligations. An individual in a supervisory position from the program where the individual's experience or training was gained would complete the form. While debating the value of the existing letter requirements, the MPSC noted that the committee was unlikely to reject an application based solely on the contents of these two letters, which often simply copy the necessary language directly from the bylaws rather than providing any assessment of the proposed individual's qualifications. Programs have had issues previously obtaining these letters, particularly if a fellowship was completed many years ago and the fellowship director is retired or deceased. Nevertheless, the MPSC concluded that the certification of an individual with knowledge of the proposed primary's previous experience was valuable to the application review process. Therefore, the MPSC suggested replacing the existing letters with an OPTN produced certification form. The MPSC certification would provide additional evidence and support for the accuracy of the experience logs submitted with the application. In addition, the MPSC concluded that the proposed revisions requiring recent experience to meet the surgeon and physician requirements and the production of an OPTN form that could be submitted electronically would significantly reduce, if not eliminate, the difficulties programs have encountered in obtaining letters.

Letter of qualification

The fourth element retains the existing requirement for the proposed individual to provide a letter of qualification detailing his or her training and experience in transplantation. The MPSC concluded that the letter of qualification is helpful in gauging the proposed individual's own assessment of their skills and training that have prepared them for the position, and the level of commitment to transplant and the program. In addition, the submission of the letter of qualification does not constitute a significant burden on the program and applicant.

OPTN orientation curriculum

The MPSC has proposed a new requirement for completion of an OPTN orientation curriculum for individuals who have not previously served as a primary surgeon or primary physician for any organ type. The MPSC has suggested that the yet to be developed OPTN orientation curriculum could include education on the role of the OPTN, OPTN bylaws and policies, the transplant system, and the role and responsibilities of the program primaries. The MPSC initially proposed the idea of an OPTN orientation curriculum when considering options for proposed individuals who appeared qualified but who had gained all of their transplant experience outside of the United States transplant system. Upon further discussion, MPSC members also concluded that this curriculum would be invaluable to individuals moving into the role of a primary surgeon or physician for the first time assuming the responsibility for their program's compliance with OPTN obligations. The curriculum would provide an important foundation for success in the primary surgeon or physician role.

Conditional approval for primary surgeons and physicians

A conditional pathway allows a physician or surgeon to serve as the primary for a limited time while gaining additional experience necessary to qualify as the primary, or while the program is recruiting an alternative physician or surgeon for the primary position. The conditional pathways require that the surgeon or physician meet all requirements for being a qualified surgeon or physician under the policies developed by the OPTN under §121.4, other than the experience requirements for a certain number of transplants or procurements for surgeons or a certain number of patients for which care was provided for physicians that would be required for a primary. In addition, the conditional pathways require that the surgeon or physician have spent a minimum amount of time on an active transplant service; and that the program establish a mentorship or consulting agreement with a primary from another transplant program and submit periodic reports to the OPTN detailing the program's transplant activity

and outcomes and the surgeon or physician's progress in meeting requirements or the program's progress recruiting an alternative. If a primary physician or surgeon is approved under the conditional pathway, the transplant program's approval status is also conditional. In those instances where the surgeon or physician may be conditionally approved, only one, either the surgeon or physician, can be approved under a conditional pathway. The current bylaws contain conditional approval experience pathways as shown in the table below.

	Primary Surgeon	Primary Physician
Heart		X
Kidney		X
Liver		X
Intestine	X	X
Lung		X
Pancreas		X
Pediatric components of Heart, Kidney and Liver programs	X	X

The MPSC supports expanding the conditional pathways to surgeons in all programs where a conditional pathway exists for physicians. However, the MPSC is proposing that the use of the conditional pathways be limited to key personnel changes where the change is occurring due to a sudden vacancy in the position. Examples of acceptable situations would be the sudden death or departure of an existing primary with little to no notice. Through the use of a conditional pathway in these circumstances, the program can continue to provide access to transplant to patients on its waiting list while being monitored for quality control and progress meeting the requirements through periodic reporting to the MPSC. The MPSC does not support the use of a conditional pathway that would accept experience levels lower than the minimum established requirements for a primary surgeon or physician for approval of a new program or in instances where the program had sufficient notice of a departure. In other cases of key personnel changes, transplant programs should engage in succession planning in anticipation of possible primary surgeon and physician departures. The bylaws include this suggestion in the key personnel change provisions contained in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*. The MPSC is interested in feedback on the proposed changes to conditional approval and any possible unintended consequences.

Primary Transplant Surgeon Requirements

The MPSC proposes that the two current pathways, the fellowship pathway and the clinical experience pathway, be consolidated into one pathway that would require recent transplant experience, but would accept experience gained through any combination of fellowship or clinical experience. Under the proposed single pathway, surgeons who use experience gained during a surgical transplant fellowship must have completed the training at a hospital with a transplant training program accepted by the OPTN as currently defined in the bylaws. Individuals who have not served as a primary surgeon within the last 10 years would be required to provide a log of procurements performed. In addition, the MPSC proposes the addition of an OPTN orientation curriculum for those individuals that have not served as a primary surgeon within the last 10 years. The surgeon specific requirements would include:

1. The surgeon performed [#] or more [ORGAN] transplants at a designated [ORGAN] transplant program as primary surgeon, co-surgeon or first assistant within the last [#] years and participated in pre-operative assessment of [organ] transplant candidates and post-operative care of these recipients. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
2. If the surgeon has not previously served as a primary [ORGAN] transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have performed [#] or more [ORGAN] procurements as primary surgeon or first assistant. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.

The MPSC proposes to retain the requirement that a surgeon must have performed a certain number of transplants, including participation in pre-operative assessment and post-operative care, as one of the best indicators of a transplant surgeon's expertise. The language requiring pre-operative assessment and post-operative care would be consistently applied across all organ primary surgeon requirements. Providing clinical care, thereby developing clinical instincts and experience with a variety of clinical presentations and complications, is recognized as an effective tool to develop competency to serve as the surgical leader of a transplant program. Fellowship and residency requirements provide additional evidence of the value of a requirement for a certain volume of procedures.[6] [7]

The MPSC proposes removal of the current bylaw requirement that the surgeon demonstrate direct involvement in transplant patient care including an extensive list of various aspects of care, for example the following current requirement for kidney transplant surgeons "[t]he surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care. . . [including] management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care." The lists of aspects of care for all organ primary surgeons can be found in Attachment C. The MPSC concluded that these aspects of care are difficult to document and monitor and are subsumed in the requirement that the surgeon participate in "pre-operative assessment of transplant candidates and post-operative care of these recipients." The MPSC is requesting feedback on whether a requirement for participation in pre-operative assessment and post-operative care adequately addresses the range of care for primary surgeons.

[6] American Society of Transplant Surgeons, Transplant Accreditation & Certification Council's Abdominal Transplant Surgery Fellowship Requirements 2020. Retrieved https://asts.org/docs/default-source/fellowship-training/asts-fellow-requirements.pdf?sfvrsn=cdb42189_35.

[7] American Board of Thoracic Surgery, Operative Requirements. Retrieved 11/21/2020 https://www.abts.org/ABTS/CertificationWebPages/Operative_Requirements_Home_Page.aspx.

Finally, the MPSC proposes that surgeons would be required to submit a log of procurements if the surgeon has not served as a primary surgeon within the last 10 years. The MPSC recognizes that procurements are an essential part of the transplantation process with which all transplant surgeons, particularly primary surgeons, should have some experience. However, the MPSC considered that many senior surgeons do not regularly perform procurements. As addressed in the stratification discussion above, the MPSC retained the requirement for a procurement log but limited it to only those surgeons who had not previously served as a primary surgeon, thereby ensuring that all primary surgeons have performed procurements but not requiring a seasoned clinician to repeatedly document an area of experience where recency may not be as important. The MPSC is requesting feedback on whether the 10 year time frame is an appropriate limitation for exemption from documentation of procurements for surgeons who have previously served as a primary transplant surgeon.

The number of required transplants and the number of years in which the transplants were performed and the number of procurements will be organ-specific and will be determined in collaboration with the OPTN organ-specific committees in phase two of the project.

Primary Transplant Physician Requirements

The MPSC proposes that the multiple current pathways for primary transplant physicians in the bylaws be consolidated into one pathway that would allow documentation of recent experience providing care to transplant recipients and participating in the evaluation of potential candidates gained through a fellowship or clinical experience or a combination of both. Physicians who use experience gained during a fellowship must have completed the training at a hospital with a training program accepted by the OPTN. The requirements for kidney and liver primary physicians would have a second pathway for pediatricians that would combine the current three pediatric bylaw pathways. Only individuals who had not served as a primary physician within the last 10 years would be required to provide a log of at least one observation of a transplant and one observation of a procurement. In addition, the MPSC proposes the addition of an OPTN orientation curriculum for those individuals that have not served as a primary physician within the last 10 years. The physician-specific requirements would include:

1. The physician has been directly involved within the last [#] years in the primary care of [#] or more newly transplanted [ORGAN] recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant and participated in pre-operative care of the patient. This clinical experience must be gained as the primary [ORGAN] transplant physician or under the direct supervision of a [ORGAN] transplant physician and in conjunction with an [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has been directly involved in the evaluation of [#] potential [ORGAN] recipients, including participation in selection committee meetings. These potential [ORGAN] recipient evaluations must be documented in a log that includes the evaluation date of each potential recipient and is signed by the primary physician, fellowship director, division chief, or department chair from the program where the physician gained this experience.

3. If the proposed physician has not previously served as a primary [ORGAN] transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have observed at least 1 [ORGAN] transplant and at least 1 [ORGAN] procurement. The observations must be documented in a log that includes the date of transplant or procurement. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.

The MPSC retained the requirement that a physician must have provided care for a certain number of newly transplanted recipients, followed these patients for at least 3 months post-transplant and participated in pre-operative care of the patient as one of the best indicators of a transplant physician's expertise. In addition, the MPSC proposes to include a requirement for involvement in the evaluation of patients, including participation in selection committee meetings, for all primary physicians. This is currently a requirement for kidney primary physicians and is an integral aspect of the transplant physician role. Providing clinical care, thereby developing clinical instincts and experience with a variety of clinical presentations and complications, is recognized as an effective tool to develop competency to serve as the medical leader of a transplant program. Fellowship and residency requirements provide additional evidence of the value of a requirement for a certain volume of patient care.[8] [9]

The MPSC proposes removal of the current bylaw requirement that the physician demonstrate direct involvement in an extensive list of various aspects of care, for example the following current requirement for kidney transplant physicians "[t]he physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care. . . [including] management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care." The lists of aspects of care for all organ primary physicians can be found in Attachment C. The MPSC concluded that these aspects of care are difficult to document and monitor and are subsumed in the requirement that the physician participate in evaluations, pre-operative care and post-transplant care. The MPSC is requesting feedback on whether a requirement for participation in evaluations, pre-operative care and post-transplant care adequately addresses the range of care for primary physicians.

The MPSC retained the requirement for a physician to observe a transplant and a procurement but limited this requirement to one observation of each and to physicians who had not previously served as a primary physician in the last 10 years. Observing transplant and procurement procedures provides a physician who will serve as one of the program leaders with an understanding and appreciation for the entire process of transplantation. However, the MPSC does not believe that it is necessary for a physician to repeatedly document this experience. The MPSC is requesting feedback on whether the 10 year time frame is an appropriate limitation for exemption from documentation of observations for physicians who have previously served as a primary transplant physician.

[8] American Society of Transplantation, Transplant Nephrology Fellowship Training Accreditation Program, LLC, Fellowship Program Details 2015. Retrieved https://www.txnephaccreditation.org/fellowship-program-details.
[9] American Board of Internal Medicine, Internal Medicine and Subspeciality Policies 2020. Retrieved https://www.abim.org/certification/policies/internal-medicine-subspecialty-policies/internal-medicine.aspx.

The number of transplant recipients cared for and the number of evaluations required, as well as the time period in which those should be done, will be organ-specific and will be determined in collaboration with the OPTN organ-specific committees.

Foreign Equivalency

Background on Board Certification Equivalency

With the retention of a requirement for appropriate American or Canadian board certification, the MPSC recognizes a need for an appropriate pathway for individuals trained outside the United States and Canada. Historically, the evaluation of an equivalent to board certification for individuals trained outside the United States and Canada has been difficult to develop.

For many years, the OPTN bylaws simply stated the requirement for board certification and tacked on the phrase "or the foreign equivalent." The MPSC had difficulty determining what training or certification was equivalent, which led to inconsistency often based on the background and experience of the MPSC membership at any one time. Importantly, the vagueness of the language made it difficult for members to assess whether a foreign trained individual would be eligible to serve in a primary role.

In September 2017, a new alternative to board certification was implemented. Under the new pathway, an individual who is not board certified can qualify if the individual is ineligible for American board certification and the program provides:

- A plan for continuing education comparable to American board maintenance of certification
- Two letters of recommendation from directors of designated transplant programs not employed by the applying hospital.

Background on Transplant Experience Equivalency

Prior to September 2017, the bylaws allowed for the submission of documentation of transplant experience "at a designated [organ] transplant program or its foreign equivalent." The proposal implemented in September 2017 removed the reference to foreign equivalent requiring that all case experience occur at an OPTN designated transplant program. In the 2015 briefing paper proposing this change, the Joint Society Work Group noted that standards vary widely in transplant programs outside the United States and it is difficult to assure the vigor and quality of experience gained at those programs is equivalent to United States' programs. The briefing paper noted that under the foreign equivalent language, members are not able to determine if a proposed individual is qualified to serve as a primary surgeon or physician until the MPSC's final decision on the application. In its recent discussions on this topic, the MPSC also indicated it is important for individuals serving as primary surgeon and physician to have experience with the United States transplant system and expressed concerns about an individual whose experience is exclusively outside the United States stepping into the role of primary physician or surgeon.

Alternatives Considered and Request for Feedback

A number of issues have arisen with the current bylaws that have resulted in unintended consequences including the use of the alternative to board certification in situations for which it was not intended, and the rejection of an application for a proposed individual who appeared well qualified but whose transplant experience was gained outside of the United States. Applications have been submitted proposing individuals who lack American board certification not because they trained outside the United

States but because they are ineligible for the relevant American board certification. For example, an individual who completed a fellowship that is not accepted as qualifying was ineligible to take the necessary board exam. In another instance, an individual who trained as a surgeon was proposed for a primary physician position and was not eligible to take the medicine board exam. The MPSC also was required under the current bylaws to reject an application for an individual who could not meet the experience requirements using experience at an OPTN designated transplant program but had extensive experience at a recognized high performing transplant hospital outside the United States. The MPSC has observed that an individual can qualify as a primary surgeon using experience gained during a Canadian fellowship under the current primary surgeon fellowship pathway but the Canadian fellowship director would not be able to qualify using experience at a Canadian hospital under the clinical experience pathway.

The MPSC has considered a number of alternatives that would provide individuals who trained or obtained clinical experience outside the United States a viable pathway to qualify for a primary role. The MPSC wants to ensure that the requirements within such a pathway are equivalent to the rigorousness demanded of individuals who have trained and gained experience in the United States. The MPSC wants the requirements to be as objective and clearly defined as possible in order to provide the necessary guidance and predictability to members who are determining the eligibility of an individual to serve as the primary. At the same time, the MPSC wants the requirements to provide necessary flexibility to accommodate an almost infinite combination of foreign training and experience. Unfortunately, the MPSC has not been able to identify a comprehensive, authoritative source that evaluates equivalency of medical training or experience across the world. In order to provide as much opportunity for qualified individuals with foreign training or experience, some level of predictability will need to be sacrificed. The MPSC discussed the following alternatives:

- Retain the current alternative to board certification, but fix the language regarding ineligibility for American board certification to reflect the original proposal's intent, potentially add a requirement that the individual has met the experience requirements at an OPTN designated transplant program, and retain the current requirements for a plan for CME that is equivalent to requirements for board certified individuals and two letters of recommendation.
- Require completion of a transplant fellowship as an alternative to board certification.
- Require the submission of documentation that demonstrates the completion of an equivalent board or specialty certification, including documentation demonstrating equivalency.
- Require the submission of experience logs from outside United States with demonstration of acceptable 1 year survival and completion of an OPTN orientation curriculum for individuals with experience outside the United States.
- For both board certification and experience, use a similar process to the alternative pathways for predominately pediatric programs that requires submission of documentation of training and experience with an explanation of how the training or experience is equivalent, letters of recommendation from primary surgeons or physicians at OPTN designated transplant programs, completion of an OPTN orientation curriculum if no experience at an OPTN designated transplant program, and participation in an informal discussion with a MPSC subcommittee.

The MPSC is interested in feedback on the above options and any additional suggestions for how to provide a viable option for individuals who trained or gained experience outside the United States while ensuring that the requirements are equivalent to the rigorousness demanded of individuals who have trained and gained experience in the United States. Please consider the following questions:

- How does one evaluate whether an individual has equivalent training to a board certified practitioner?
- Should an individual proposed as primary be required to have some experience with the US transplant system? If yes, for what time period or level of experience?
- Do you support any of the alternatives suggested by the MPSC or a combination of these alternatives? Do you have other suggested options or are there other published standards that could be used to evaluate the qualifications of individuals who trained or gained experience outside the United States?

Conclusion

The MPSC has evaluated the current transplant program primary surgeon and physician training and experience bylaw requirements and is proposing changes to the general format used for development of the organ-specific primary surgeon and physician requirements. During its evaluation of the bylaw requirements, the MPSC considered feedback from members, the MPSC's experience reviewing key personnel applications, current practice and qualifications as evidenced in transplant fellowship requirements, and revisions needed to implement the OPTN contract task for periodic review for compliance with OPTN membership related bylaws.

The Committee is requesting feedback on both the general proposed revisions to the format for transplant program key personnel experience and training requirements, and specifically on the following questions:

- Do you support the following suggested changes to the training and experience requirements for primary surgeons and primary physicians? Can you identify any unintended consequences if the suggested changes are adopted?
    - Consolidation of the fellowship and clinical experience pathways into one pathway that includes a requirement for recent experience and will accept both fellowship and clinical experience.
    - Using an electronic, OPTN-produced certification form in place of the letters of reference and recommendation.
    - Limiting procurement requirement for surgeons and observation requirements for physicians to individuals who have not served as primary surgeons or physicians in the last 10 years. Is a 10 year time frame an appropriate time limitation for exemption of individuals who have previously served as a primary surgeon or physician?
    - Expanding use of conditional approval pathways to surgeons, in addition to physicians, but limiting the use of the conditional approval pathways to circumstances where there is an unanticipated vacancy with short notice.
    - Eliminating the requirements for surgeons and physicians to document participation in an extensive list of aspects of transplant patient care (*See Attachment C for the current required organ-specific list of aspects of transplant patient care*). Does participation in pre-operative assessment and post-operative care adequately address the range of care for primary surgeons? Does participation in primary care of newly transplanted recipients for a minimum of 3 months, participation in pre-operative care of patients and direct involvement in the evaluation of potential candidates adequately address the range of care for primary physicians?
- Do you support the addition of an OPTN Orientation Curriculum? If yes, what topics should be covered in the OPTN Orientation Curriculum?

- For individuals with foreign training or experience:
    - How does one evaluate whether an individual has equivalent training to a board certified practitioner?
    - Should an individual proposed as primary be required to have some experience with US transplant system? If yes, for what time period or level of experience?
    - Do you support any of the alternatives suggested by the MPSC or a combination of these alternatives? Do you have other suggested options or are there other published standards that could be used to evaluate the qualifications of individuals who trained or gained experience outside the United States?
- For a future project to better define the current requirement that primary surgeons and physicians be "on site":
    - What should be the responsibilities of the primary surgeon and primary physician? What level of commitment to a transplant program must a surgeon and physician demonstrate to fulfill the role of primary surgeon and physician?

Attachment A: Transplant Program Key Personnel Draft Format Language

X.1 Membership and Personnel Requirements for [ORGAN] Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated [ORGAN] transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated [ORGAN] transplant program.

All [ORGAN] transplant programs must also meet general membership requirements, which are described in *Appendix D: Transplant Hospital Membership and Designated Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership and Designated Transplant Program Application and Review* of these Bylaws.

X.2 Primary [ORGAN] Transplant Surgeon, and Primary [ORGAN] Transplant Physician

The program must identify a qualified primary transplant surgeon and a qualified primary transplant physician, as described below. The primary surgeon and primary physician must submit a detailed Program Coverage Plan to the OPTN. For detailed information about the Program Coverage Plan, see *Appendix D, Section XXX: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

X.3 Primary [ORGAN] Transplant Surgeon Requirements

A designated [ORGAN] transplant program must have a primary surgeon who meets *all* of the following requirements through the surgeon's fellowship or through acquired clinical experience (including accumulated training during any surgical transplant fellowships). Surgeons who are using experience gained during an applicable fellowship must have completed training at a hospital with an [ORGAN] transplant training program accepted by the OPTN as described in *Section X.X: Approved [ORGAN] Transplant Surgeon and Physician Fellowship Training Programs*.

1. The surgeon must
   a. Have an M.D., D.O., or equivalent degree from another country
   b. Have a current license to practice medicine in the hospital's state or jurisdiction
   c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
   d. Be on site at this hospital.
2. The surgeon must have current certification by the American Board of [Thoracic] Surgery, the American Board of Osteopathic Surgery, [OTHER ORGAN APPROPRIATE BOARDS] or the Royal College of Physicians and Surgeons of Canada. (*See Attachment B for currently accepted board certification for each organ*).

3. The surgeon performed [#] or more [ORGAN] transplants at a designated [ORGAN] transplant program as primary surgeon, co-surgeon or first assistant within the last [#] years and participated in pre-operative assessment of [organ] transplant candidates and post-operative care of these recipients. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
4. An OPTN form that certifies that the surgeon meets the requirements for a [ORGAN] primary surgeon, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary surgeon, fellowship director, division chief, or department chair from the program where the surgeon's experience or training was gained must be submitted.
5. The surgeon must provide a letter that details the training and experience the surgeon has gained in [ORGAN] transplantation.
6. If the surgeon has not served as a primary [ORGAN] transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have performed [#] or more [ORGAN] procurements as primary surgeon or first assistant. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
7. If the surgeon has not served as a primary transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have completed the OPTN orientation curriculum for primary transplant surgeons.

X.4 Primary [ORGAN] Transplant Physician Requirements

A designated [ORGAN] transplant program must have a primary physician who meets the following requirements. Physicians can meet the requirements for a primary [ORGAN] transplant physician during the physician's transplant fellowship or through acquired clinical experience (including accumulated training during any transplant fellowships). Physicians who are using experience gained during a fellowship must have completed training at a hospital with an [ORGAN] transplant training program accepted by the OPTN as described in *Section X.X: Approved [ORGAN] Transplant Surgeon and Physician Fellowship Training Programs*.

1. The physician must
   a. Have an M.D., D.O., or equivalent degree from another country
   b. Have a current license to practice medicine in the hospital's state or jurisdiction
   c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
   d. Be on site at this hospital.
2. The physician must have current board certification in [ORGAN APPROPRIATE BOARDS]. (*See Attachment B for currently accepted board certification for each organ*).
3. The physician must meet the requirements of either General Pathway outlined in X.4.A below or the Pediatric Pathway outlined in X.4.B below

A. General Pathway

1. The physician has been directly involved within the last [#] years in the primary care of [#] or more newly transplanted [ORGAN] recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant and participated in pre-operative care of the patient. This clinical experience must be gained as the primary [ORGAN] transplant physician or under the direct supervision of a [ORGAN] transplant physician and in conjunction with an [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has been directly involved in the evaluation of [#] potential [ORGAN] recipients, including participation in selection committee meetings. These potential [ORGAN] recipient evaluations must be documented in a log that includes the evaluation date of each potential recipient and is signed by the primary physician, fellowship director, division chief, or department chair from the program where the physician gained this experience.
3. An OPTN form that certifies that the physician meets the requirements for a [ORGAN] primary physician, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary physician, fellowship director, division chief, or department chair from the program where the physician's experience or training was gained must be submitted.
4. The physician provides a letter that details the training and experience the physician has gained in [ORGAN] transplantation.
5. If the proposed physician has not served as a primary [ORGAN] transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have observed at least 1 [ORGAN] transplant and at least 1 [ORGAN] procurement. The observations must be documented in a log that includes the date of transplant or procurement. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
6. If the proposed physician has not served as a primary transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have completed the OPTN orientation curriculum for primary transplant physicians.

B. Pediatric Pathway (Kidney and Liver only)

[*The MPSC is proposing the consolidation of the three existing pediatric pathways for kidney and liver primary physicians into one following the same format as the general pathway.*]

X.6 Conditional Approval for [ORGAN] Program

As part of a key personnel change at an approved designated [ORGAN] transplant program, a surgeon can serve conditionally as the primary [ORGAN] transplant surgeon or a physician can serve conditionally as the primary [ORGAN] transplant physician for a maximum of 12 months if the conditions below are met. Conditional approval of a primary transplant surgeon or primary transplant physician results in a change in status for the transplant program to conditional approval. The MPSC may consider on a case-by-case basis granting a # month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete the requirements within the 12-month conditional approval period.

A. Conditional Approval for Primary Transplant Surgeon

A surgeon can serve as the primary [ORGAN] transplant surgeon for a maximum of 12 months if all of the following conditions are met:

1. The program has a qualified primary [ORGAN] transplant physician who meets all of the requirements described in *X.4 Primary [ORGAN] Transplant Physician Requirements*.
2. The change in primary [ORGAN] transplant surgeon was caused by an unanticipated vacancy in the position with short notice.
3. The surgeon must
    a. Have an M.D., D.O., or equivalent degree from another country
    b. Have a current license to practice medicine in the hospital's state or jurisdiction
    c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
    d. Be on site at this hospital.
4. The surgeon must have current certification by the American Board of [Thoracic] Surgery, the American Board of Osteopathic Surgery, [OTHER ORGAN APPROPRIATE BOARDS] or the Royal College of Physicians and Surgeons of Canada. (*See Attachment B for currently accepted board certification for each organ.*)
5. The surgeon has 12 months experience on an active [ORGAN] transplant service as the primary [ORGAN] transplant surgeon or under the direct supervision of a qualified [ORGAN] transplant surgeon along with a [ORGAN] transplant physician at a designated [ORGAN] transplant program. These 12 months of experience must be acquired within the last 2 years.
6. The surgeon develops a formal mentor relationship with a primary [ORGAN] transplant surgeon at another approved [ORGAN] transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.
7. The surgeon performed at least [SOME # LESS THAN THE REQUIRED FOR FULL APPROVAL] [ORGAN] transplants at a designated [ORGAN] transplant program as primary surgeon, co-surgeon or first assistant within the last [#] years and participated in pre-operative assessment of [organ] transplant candidates and post-operative care of these recipients. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
8. An OPTN form that certifies that the physician meets the requirements for a [ORGAN] primary physician, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary physician, fellowship director, division chief, or department chair from the program where the physician's experience or training was gained must be submitted.
9. The surgeon must provide a letter that details the training and experience the surgeon has gained in [ORGAN] transplantation.
10. If the surgeon has not served as a primary [ORGAN] transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have performed [#] or more [ORGAN] procurements as primary surgeon or first assistant. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.

11. If the surgeon has not served as a primary transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have completed the OPTN orientation curriculum for primary transplant surgeons.
12. The transplant program submits activity reports to the OPTN every 2 months describing the transplant activity, transplant outcomes, surgeon recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the surgeon is making sufficient progress to meet the requirements for full approval, or that the program is making sufficient progress in recruiting a surgeon who meets all requirements for primary [ORGAN] transplant surgeon and who will be on site and approved by the MPSC to assume the role of primary surgeon by the end of the 12 month conditional approval period.

B. Conditional Approval for Primary Transplant Physician

A surgeon can serve as the primary [ORGAN] transplant physician for a maximum of 12 months if all of the following conditions are met:

1. The program has a qualified primary [ORGAN] transplant surgeon who meets all of the requirements described in *X.3 Primary [ORGAN] Transplant Surgeon Requirements*.
2. The change in primary [ORGAN] transplant physician was caused by an unanticipated vacancy in the position with short notice.
3. The physician must
    a. Have an M.D., D.O., or equivalent degree from another country
    b. Have a current license to practice medicine in the hospital's state or jurisdiction
    c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
    d. Be on site at this hospital.
4. The physician must have current board certification in [ORGAN APPROPRIATE BOARDS]. (*See Attachment B for currently accepted board certification for each organ*).
5. The physician has 12 months experience on an active [ORGAN] transplant service as the primary [ORGAN] transplant physician or under the direct supervision of a qualified [ORGAN] transplant physician along with a [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. These 12 months of experience must be acquired within the last 2 years.
6. The physician develops a formal mentor relationship with a primary [ORGAN] transplant physician at another approved designated [ORGAN] transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.
7. The physician has been directly involved within the last [#] years in the primary care of at least [SOME # LESS THAN THE REQUIRED FOR FULL APPROVAL] newly transplanted [ORGAN] recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant and participated in pre-operative care of the patient. This clinical experience must be gained as the primary [ORGAN] transplant physician or under the direct supervision of a [ORGAN] transplant physician and in conjunction with an [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.

8. The physician has been directly involved in the evaluation of at least [SOME # LESS THAN THE REQUIRED FOR FULL APPROVAL] potential [ORGAN] recipients, including participation in selection committee meetings. These potential [ORGAN] recipient evaluations must be documented in a log that includes the evaluation date of each potential recipient and is signed by the primary physician, division chief, or department chair from the program where the physician gained this experience.
9. An OPTN form that certifies that the physician meets the requirements for a [ORGAN] primary physician, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary physician, fellowship director, division chief, or department chair from the program where the physician's experience or training was gained must be submitted.
10. The physician provides a letter that details the training and experience the physician has gained in [ORGAN] transplantation.
11. If the proposed physician has not served as a primary [ORGAN] transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have observed at least 1 [ORGAN] transplant and at least 1 [ORGAN] procurement. The observations must be documented in a log that includes the date of transplant or procurement. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
12. If the proposed physician has not served as a primary transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have completed the OPTN orientation curriculum for primary transplant physicians.
13. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the requirements for full approval, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary [ORGAN] transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

X.7 Approved [ORGAN] Transplant Surgeon and Physician Fellowship Training Programs

A. Transplant Surgeon Fellowship Training Programs

Surgeons qualifying as primary transplant surgeon based on completion of a formal surgical transplant fellowship must complete their training at a fellowship program approved by the [ORGAN APPROPRIATE ORGANIZATIONS] or another recognized fellowship training program accepted by the OPTN that meets *all* of the following criteria:

1. The program is at a transplant hospital that transplants two or more organs, including [ORGAN]s.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least [#] [ORGAN] transplants during each year of the fellowship training.

B. Transplant Physician Fellowship Training Programs ***[Some current organ specific requirements only include requirements for surgical transplant fellowships]***

Physicians qualifying as primary transplant physician based on completion of a formal transplant fellowship must complete their training at a fellowship program approved by the [ORGAN APPROPRIATE ORGANIZATIONS], or another recognized fellowship training program accepted by the OPTN that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including [ORGAN]s.
2. The program is at a hospital that has an ACGME approved [SPECIALTY] program.
3. The program performs at least [#] [ORGAN] transplants per year if the program is training one transplant [SPECIALTY] fellow, and performs at least [#] additional [ORGAN] transplants per year for each additional fellow it trains.
4. [KIDNEY EXAMPLE]The program's curriculum must include training and experience in end-stage renal disease, training in the selection of appropriate transplant recipients and donors, experience in the immediate and long term care of the transplant recipient, and training in the performance of kidney transplant biopsies. Additionally there must be an emphasis on the management of immunosuppressive agents and the evaluation of kidney transplant dysfunction.
5. [KIDNEY EXAMPLE] The program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period. The kidney trainee must primarily manage the transplant recipient's medical care including hypertension, diabetes, and dialytic problems. Trainees must also serve as a primary member of the transplant team and participate in making decisions about immunosuppression.

Attachment B: Board certifications currently accepted for each organ

Primary Surgeons:	
Organ	**Boards accepted**
Kidney	American Board of Surgery American Board of Urology, conditional approval if pending American Board of Osteopathic Surgery Royal College of Physicians and Surgeons of Canada
Liver	American Board of Surgery American Board of Urology, conditional approval if pending American Board of Osteopathic Surgery Royal College of Physicians and Surgeons of Canada
Intestine	American Board of Surgery American Board of Osteopathic Surgery Royal College of Physicians and Surgeons of Canada
Pancreas	American Board of Surgery American Board of Urology, conditional approval if pending American Board of Osteopathic Surgery Royal College of Physicians and Surgeons of Canada
Heart	American Board of Thoracic Surgery, conditional approval if pending Royal College of Physicians and Surgeons of Canada, Thoracic Surgery
Lung	American Board of Thoracic Surgery, conditional approval if pending Royal College of Physicians and Surgeons of Canada, Thoracic Surgery

Primary Physicians:	
Organ	**Boards accepted**
Kidney	current certification in nephrology by: American Board of Internal Medicine American Board of Pediatrics Royal College of Physicians and Surgeons of Canada
Liver	current board certification in gastroenterology, current board certification in transplant hepatology, or a current pediatric transplant hepatology certification of added qualification by: American Board of Internal Medicine American Board of Pediatrics Royal College of Physicians and Surgeons of Canada
Intestine	current board certification in gastroenterology by: American Board of Internal Medicine American Board of Pediatrics Royal College of Physicians and Surgeons of Canada

Primary Physicians:		
Pancreas	current board certification in nephrology, endocrinology, or diabetology by: American Board of Internal Medicine American Board of Pediatrics Royal College of Physicians and Surgeons of Canada
Heart	current certification in adult or pediatric cardiology or current board certification in advanced heart failure and transplant cardiology by: American Board of Internal Medicine American Board of Pediatrics Royal College of Physicians and Surgeons of Canada
Lung	current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by: American Board of Internal Medicine American Board of Pediatrics Royal College of Physicians and Surgeons of Canada

Attachment C: Lists of aspects of care a surgeon or physician is currently required to document but are not included in the proposed framework

Primary Surgeons:	
Organ	**Aspects of patient care required**
Kidney	Management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
Liver	Management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
Intestine	Management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
Pancreas	Management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
Heart	Performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
Lung	Care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.

Primary Physicians:	
Organ	**Aspects of patient care required**
Kidney	Management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
Liver	management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
Intestine	Management of patients with intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
Pancreas	Management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
Heart	Care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
Lung	Care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.

OPTN

White Paper

General Considerations in Assessment for Transplant Candidacy

OPTN Ethics Committee

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General Considerations in Assessment for Transplant Candidacy

Sponsoring Committee: *Ethics*
Public Comment Period: *January 21, 2021 – March 23, 2021*

Executive Summary

Transplant programs in the United States evaluate the suitability of potential transplant candidates using listing criteria developed by the transplant programs. The criteria are both medical and non-medical in nature. The use of non-medical criteria in evaluating patients for transplantation can affect the decision to list a potential transplant candidate. This white paper offers an analysis of ethical considerations associated with non-medical criteria commonly used by transplant programs in listing decisions. It addresses use of life expectancy, potentially injurious behaviors, adherence, repeat transplantation, incarceration status, immigration status, and social support as transplant evaluation criteria. This list is neither exhaustive nor immutable.

The intent of this white paper is to advise transplant programs and provide them with information about the considerations discussed herein. The Organ Procurement and Transplantation Network (OPTN) has the authority to publish this white paper based on the Final Rule's requirement that "a transplant hospital which is an OPTN member may list individuals, consistent with the OPTN criteria…"[1] Likewise, the Final Rule states that the OPTN standardizes "the criteria…for adding individuals to, and removing candidates from, organ transplant waiting lists."[2] This white paper supports the standardization of criteria by encouraging transplant programs to consider the ethical implications of commonly used criteria.

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

Background

Non-medical factors relevant to transplant evaluations and listing decisions often include, but may not be limited to, psychosocial factors (e.g., social support, patient adherence).[3] Use of non-medical transplant evaluation criteria remains an area of concern to many in the transplant community.[4,5] Non-medical criteria are thought, by some, to uphold the principle of utility by selecting candidates who may have better adherence or post-transplant outcomes. Ethical concerns with using non-medical criteria to evaluate potential transplant candidates involve equity and justice.[6,7,8,9] Inconsistent and subjective use of non-medical criteria without clear standards is likely to result in the inconsistent distribution of medical good among potential beneficiaries, undermining equal respect and concern for individuals.

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

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

Purpose

In deciding to pursue a revised version of the General Considerations in Assessment for Transplant Candidacy analysis, the Committee determined that there may be aspects of the 2015 version that are

[3] 42 CFR §482.90.

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

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

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

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

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

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

outdated or could benefit from revision and updates. For example, the discussion of "Alternative Therapies" was removed from this re-write because consideration of alternative therapies before proceeding with transplantation is a common practice among programs now. In addition, new criteria were added, including incarceration status and social supports. The following discussion offers an overview of the ethical challenges associated with the use of non-medical criteria.

This analysis relies on the three ethical principles identified in the *Ethical Principles in the Allocation of Human Organs*, which include utility, justice, and respect for persons.[10] As described in the *Ethical Principles…*, utility refers to the maximization of net benefit to the community and justice refers to the fair pattern of distribution of benefits. The principle of respect for persons primarily conveys the concept of respect for autonomy. Transplant evaluations should balance justice requirements and respect for persons with utility considerations, including efforts to avoid futility.[11]

The following white paper is submitted under the authority of the OPTN Final Rule, which states that "a transplant hospital which is an OPTN member may list individuals, consistent with OPTN criteria…"[12] Furthermore, the OPTN has the authority under the Final Rule to standardize the criteria that are used "for adding individuals to, and removing candidates from, organ transplant waiting lists."[13] This white paper addresses common criteria transplant programs use for adding and removing individuals from the waiting list. Encouraging transplant programs that use such criteria to consider, at a minimum, the ethical implications creates a minimum standard for use of the criteria.

Criteria Considered

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

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

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

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

- Incarceration status
- Immigration status
- Social support

NOTA and Final Rule Analysis

Determining suitability for transplant, and thus, determining whether a patient should be listed as a candidate with the OPTN, is a decision that lies with transplant programs.[14] While transplant hospitals primarily rely on objective, measurable medical criteria, they also often incorporate psychosocial, non-medical considerations into their determination of suitability for listing. This paper provides an ethical analysis of some of those considerations.

Conclusion

Use of non-medical criteria continues to raise ethical concerns insofar as they commonly: (1) lack clear standards and thresholds; (2) are inconsistently applied; (3) are susceptible to stereotyping and instrumental value judgments; (4) are not transparent to patients; and (5) are not consistently supported by evidence. As such, transplant evaluations should not exclusively rely on non-medical criteria. When non-medical criteria are included in listing considerations, transplant programs should apply them without bias. This white paper is intended to help advise programs on the use of certain non-medical criteria.

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

White Paper

General Considerations in Assessment for Transplant Candidacy

~~Reviewed in 2015~~

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

~~Preamble~~

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

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

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

~~Life Expectancy~~

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

~~Organ Failure Caused by Behavior~~

~~In social and medical venues, debate continues to focus upon alcoholism, drug abuse, smoking, eating disorders and other behaviors as diseases or character flaws. Such behaviors are associated with disease~~

~~processes in many adults. The Ethics Committee has historically supported the conclusion that past behavior that results in organ failure should not be considered a sole basis for excluding transplant candidates. However, additional discussion of this issue in a societal context may be warranted.~~

~~Compliance/Adherence~~

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

~~Repeat Transplantation~~

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

~~Alternative Therapies~~

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

Revised in 2020

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

Preamble

Transplant programs in the United States evaluate the suitability of potential transplant candidates using listing criteria developed by the transplant programs. The criteria are both medical and non-medical in nature. The use of non-medical criteria in evaluating patients for transplantation can affect the decision to accept a potential transplant candidate. This white paper offers an analysis of ethical considerations associated with non-medical criteria commonly used by transplant programs in listing decisions. It addresses use of life expectancy, potentially injurious behaviors, adherence, repeat transplantation, incarceration status, immigration status, and social support as transplant evaluation criteria. This list is neither exhaustive nor immutable.

Non-medical factors relevant to transplant evaluations and listing decisions often include, but may not be limited to, psychosocial factors (e.g., social support, patient adherence).[15] Use of non-medical

[15] 42 CFR §482.90.

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

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

This analysis relies on the three ethical principles identified in the *Ethical Principles in the Allocation of Human Organs*, which include utility, justice, and respect for persons.[22] As described in the *Ethical Principles…*, utility refers to the maximization of net benefit to the community and justice refers to the fair pattern of distribution of benefits. The principle of respect for persons primarily conveys the concept of respect for autonomy. Transplant evaluations should balance justice requirements and respect for persons with utility considerations, including efforts to avoid futility.[23]

The OPTN has reviewed and revised its historical position statement on transplant candidacy for considerations, including non-medical criteria, on several occasions, most recently in 2015.[24][25] At the

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

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

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

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

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

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

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

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

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

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

time, the OPTN provided ethical analyses of several criteria cited in this document, including life expectancy, organ failure caused by behavior, compliance/adherence, and repeat transplantation. In deciding to pursue a revised version, it was determined that there may be aspects of the 2015 version that are outdated or could benefit from revision and updates. The following discussion offers an overview of the ethical challenges associated with the use of non-medical criteria.

Life Expectancy

Supported largely by the principle of utility, as discussed in the *Ethical Principles in the Allocation of Human Organs*, potential transplant candidates with longer life expectancy may, with a successful transplant, achieve the greatest benefit in terms of years of life saved.[26] The OPTN concurs that a patient's ability to benefit from transplant should align with the organ's potential longevity. While both a patient's life expectancy and current state of health may be correlated to age, age itself should not be used to restrict transplantation owing to considerations of justice and respect for persons.[27] Concerns of justice, the ability of all persons to benefit from transplantation, such as those articulated in the Age Discrimination Act of 1975,[28] preclude federally funded programs, like the OPTN, from engaging in age discrimination. In kind, the Affordable Care Act prohibits health care programs or activities from discriminating on the basis of age alone.[29] While the use of age by itself should not be used as a sole criterion for determining eligibility for potential transplant, it is ethically permissible to consider longevity and success of the graft. Age does not offer the full picture in determining the life expectancy and it precludes the possibility of some individuals being listed who might otherwise have made good candidates, thereby not respecting their autonomy.

Potentially Injurious Behavior

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

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

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

[28] 42 U.S.C §§6101-6107.

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

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

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

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

Potentially injurious behaviors associated with negative outcomes may be partly due to personal choice and as such may involve personal responsibility or autonomy. However, these behaviors are also known to be significantly influenced by underlying psychological, genetic, economic, and systemic factors, including early life exposures – factors over which patients may have little control.[33] For example, one's diet is not a straightforward reflection of personal choice, but rather determined by several factors including one's access to a grocery store which sells healthy food. Factors predicting substance use disorders similarly are shared between genetic and social precursors, as only some are related to personal choice.[34] While potentially injurious behaviors may be due, in part, to personal choice, transplant providers should not automatically assume potential transplant candidates are solely responsible for engaging in those behaviors as they may be caused by factors over which patients do not have full control.

Excluding patients from transplantation due to potentially injurious behaviors that are influenced by factors beyond patients' control can exacerbate disparities in health and access to health care, thereby undermining justice and respect for persons in access to transplantation. Consequently, to the extent that is possible, balancing the principles of utility, justice, and respect for persons requires that considerations meant to lessen the impact of behavioral factors, such as abstinence periods for alcohol use disorder, be objective and evidence-based.[35] Considering the contribution of multifactorial factors to both behavior and subsequent organ loss, and the insufficient evidence supporting the use of some factors, the OPTN continues to affirm that evaluation and listing decisions should be driven primarily by medical benefit, and that potentially injurious behavior should not be considered a sole basis for excluding transplant candidates.[36] In other words, the mere presence of a potentially injurious behavior, such as a history of substance use, should not automatically rule one out as a potential transplant candidate, as this would violate both respect for persons and justice.

Adherence

Adherence (understood to be a bi-directional, proactive process of discussion and agreement between the patient and the medical team, on a course of therapy or management)[37] has limited objective measures. Adhering to a medical regimen post-transplant increases the likelihood of a successful transplant, increasing utility. Thus, transplanting patients who will be adherent is supported by the principle of utility. However, there are few reliable predictors of post-transplant adherence, and medical professionals commonly approach these issues inconsistently.[38]

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

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

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

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

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

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

Justice requires that a history of consistent and documented treatment non-adherence should be considered by the transplant team in the context of barriers to adherence and other medical and psychosocial criteria. A transplant program should also consider an individual's expressed willingness to follow treatment regimes. Patients may experience disparities in access to care based on geography, resources and financial status which can adversely affect both their ability to adhere to recommendations, and the implicit perceptions held by the clinicians about their ability to so adhere. Transplant program staff may evaluate these barriers and consider providing support, including ancillary services such as counseling to candidates who lack adequate resources or have psychosocial challenges.

Repeat Transplantation

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

Incarceration Status

The OPTN recognizes that incarcerated individuals, as well as individuals who are at high risk for recidivism for incarceration (as determined by evidence-based indicators such as age, poor criminal history, negative peer associations, substance use, and antisocial personality disorder),[39] face barriers to successful transplantation. The OPTN affirms its position established in the white paper, *Convicted Criminals and Transplant Evaluation* that "absent any societal imperative, one's status as a prisoner should not preclude them from consideration for a transplant; such consideration does not guarantee transplantation."[40] Additional steps should be taken to collaborate with correctional authorities to provide comprehensive post-transplant care to incarcerated individuals, should the patient be deemed a candidate for transplantation.

Immigration Status

Consistent with current OPTN policy, immigration status should not be used as a criterion in determining transplantation candidacy. Consistent with OPTN policy, a candidate's citizenship or residency status must not be considered when allocating deceased donor organs to candidates for transplantation.[41] While immigration status may be tightly intertwined with other psychosocial and financial factors that affect a person's candidacy for transplantation[42] immigration status *alone* should neither determine nor

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

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

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

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

exclude a person's candidacy for organ transplantation as these would be unduly compromise justice and respect for persons.

Many noncitizens participate in the transplant system as donors.[43] The principle of reciprocity highlights that it seems unjust for a system to use organs from a group of persons categorically excluded from access. Participation as organ donors and long-term residents in the U.S. also means that undocumented immigrants are not considered "transplant tourists" under the definition of the Declaration of Istanbul.[44]

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

Social Support

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

[43] Wightman, Aaron, and Diekema, Douglas. "Should an Undocumented Immigrant Receive a Heart Transplant?" *AMA Journal of Ethics* 17, no. 10 (2015): 909-13.
[44] Summit, Steering Committee. "Organ Trafficking and Transplant Tourism and Commercialism: The Declaration of Istanbul." *The Lancet* (British Edition) 372, no. 9632 (2008): 5-6.
[45] Barrera, Manuel. "Distinctions between Social Support Concepts, Measures, and Models." *American Journal of Community Psychology* 14, no. 4 (1986): 413-45.
[46] Gottlieb, Benjamin H, and Bergen, Anne E. "Social Support Concepts and Measures." *Journal of Psychosomatic Research* 69, no. 5 (2010): 511-20.
[47] Ladin, Keren, Daniels, Alexis, Osani, Mikala, and Bannuru, Raveendhara R. "Is Social Support Associated with Post-transplant Medication Adherence and Outcomes? A Systematic Review and Meta-Analysis." *Transplantation Reviews* 32, no. 1 (2017): 16-28.
[48] Ladin, Keren, Emerson, Joanna, Berry, Kelsey, Butt, Zeeshan, Gordon, Elisa J, Daniels, Norman, Lavelle, Tara A, and Hanto, Douglas W. "Excluding Patients from Transplant Due to Social Support: Results from a National Survey of Transplant Providers." *American Journal of Transplantation* 19, no. 1 (2019): 193-203.
[49] Ladin, Keren, Emerson, Joanna, Berry, Kelsey, Butt, Zeeshan, Gordon, Elisa J, Daniels, Norman, Lavelle, Tara A, and Hanto, Douglas W. "Excluding Patients from Transplant Due to Social Support: Results from a National Survey of Transplant Providers." *American Journal of Transplantation* 19, no. 1 (2019): 193-203.

proficiency and those who do not have flexible employment schedules. As such, use of social support to determine transplant eligibility may exacerbate socioeconomic, racial, ethnic, and gender disparities.[50]

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

Summary/Conclusion

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

[50] Browne, Teri. "The Relationship between Social Networks and Pathways to Kidney Transplant Parity: Evidence from Black Americans in Chicago." *Social Science & Medicine (1982)* 73, no. 5 (2011): 663-67.

OPTN

Proposed Strategic Plan for Public Comment

Strategic Plan 2021-2024

OPTN Executive Committee

Prepared by: Brian Shepard, OPTN Executive Director
Chelsea Rock Haynes, Board Relations (UNOS)

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Strategic Plan 2021-2024

Sponsoring Committee: *Executive*
Public Comment Period: *January 21-March 24, 2021*

Overview

The OPTN Board of Directors adopts a new strategic plan every three years, to guide the work of the OPTN and its committees. The strategic plan maintains a balance between setting high level community goals and allowing committees the flexibility to design specific policy projects

The proposed plan for 2021-24 is built around four primary goals. The most important is Goal 1: Increasing the Number of Transplants. The other three goals are Provide Equity in Access to Transplants, Promote Living Donor and Transplant Recipient Safety, and Improve Waitlisted Candidate, Living Donor, and Transplant Recipient Outcomes.

The proposed goals for 2021-2024 are similar to the high level goals in the current strategic plan except in one respect. The current strategic plan includes a high level goal for improving efficiency in the system. Discussions about the proposed strategic plan described a strong preference for projects that made the system more efficient – for the purpose of facilitating more transplants. Therefore, the initiatives that fit that criteria, efficiency in the service of transplantation, are now included in Goal 1: Increasing the number of Transplants.

Goal 1 includes continuing efforts to improve performance metrics, moving from one or two indicators to a more comprehensive dashboard approach. It also includes tools to improve utilization and increase system efficiency. It also calls on the OPTN to explore ways to increase the use of DCD organs for transplant, and to review policies to determine whether any changes are necessary to facilitate emerging organ perfusion technologies.

Goal 2, equity, includes efforts to better define requirements for multi-organ transplants, to continue the development of the Continuous Distribution policymaking approach, and to ensure diversity in the decision makers on the OPTN Board and Committees.

Goal 3, safety, includes educational and collaborative efforts to share expertise across the community in order to improve safety practices.

Goal 4, outcomes, includes data tools to better understand organ offers, and living donation and transplant outcomes. Traditionally, the difference between goals 3 and 4 – safety and outcomes – is one of timing. Safety events are short-term transplant operation issues, and outcomes refer to long-term, post-transplant graft and patient survival.

The proposed strategic plan sets targets for allocating committee resources to each of the four strategic goals, and they are not equal. The plan proposes spending half of all committee time and programming effort on projects that increase the number of transplants. The plan proposes allocating 30% to equity projects, and ten percent each to safety and outcomes projects.

Finally, the strategic plan proposes trackable metrics for each of the key goals. They should be impacted by the strategic plan initiatives, and by any other committee work in these areas, but they are not tied in a 1:1 way to specific initiatives. One initiative may impact multiple metrics, and several initiatives could all intend to move the needle on the same metric. As each committee project is developed in detail over the period covered by the plan, specific metrics and monitoring plans are described for each project.

The current plan expires in June 2021. The Board and Executive Committee began review of the current plan in the late spring of 2020, convening over 80 OPTN Board members and Committee leaders to offer feedback and guidance on prioritization of efforts. The draft plan incorporates this collective feedback and provides resource allocation weights for each.

The Executive Committee seeks public comment on whether this set of goals and their associated initiatives and metrics are appropriate and reasonably weighted. Specifically, the Committee requests the following feedback:

1) Do you agree with the Board's proposed areas of strategic focus for the 2021-2024 plan?
2) Is a goal or initiative missing from this plan that should be considered a strategic priority? Will resource allocation benchmarks need to be changed to accommodate the addition?
3) Are there goals or initiatives that should not be included in this plan? If so, should they be maintained in the OPTN's future operations or discontinued altogether?
4) Are the stated performance metrics sufficient, measurable and specific?

Proposed Strategic Plan

Goal 1: Increase the number of transplants

Resource Allocation Benchmark 50%

Core activities:

Serving as the OPTN, UNOS maintains the national transplant candidate waiting list and operates a 24/7 electronic matching system accessible to every OPO and transplant center in the country. UNOS also operates a 24/7 Organ Center, a live call center to assist OPOs and transplant centers with questions, transportation arrangements, and with placing organs.

Initiatives:

1) Improve metrics and monitoring approaches for increased collaboration and performance improvement activities when assessing transplant program and OPO performance
    a) Develop improved OPO metrics that provide an accurate assessment of OPO performance and can be leveraged as a tool to identify actionable improvement opportunities
    b) Develop a dashboard of transplant center metrics that goes beyond one-year post-transplant outcomes and avoids creating disincentives to transplant, to include measures that can be utilized to identify strategies for improvement, including monitoring of offer acceptance rates by donor age and donor type, and late declines for candidates with multiple accepted offers.
    c) Develop systemic metrics that measure the interactions between OPOs and transplant centers that identifies opportunities to increase the number of transplants.
2) Pursue policies and system tools that promote system efficiency and increase organ utilization.
    a) Expand the use of offer filters to reduce unwanted offers and increase efficient placement
    b) Reform the use of provisional yes to make it a timely, meaningful response
    c) Address wide variation in biopsy practices
    d) Expedite offers of difficult to place organs
    e) Increase seamless data exchange between members and UNetSM to reduce data burden and improve data integrity.
    f) Support the use of local recovery to increase utilization and reduce team travel
        i) Improve technology support for sharing images and information during recovery process
        ii) Develop best practices to work towards consistent expectations for local recovery
3) Increase the number of DCD donor organs recovered and transplanted by encouraging inter-organ and inter-program collaboration and the development of effective practices
4) Review policies to determine whether future changes will be necessary to encourage or facilitate machine perfusion of organs
5) Increase the effectiveness of paired living donation programs
    a) Develop policies to allow deceased donor kidneys to begin KPD chains

Key metrics:

1) A decrease in time from first organ offer and average number of offers to acceptance.
2) An increase in national offer acceptance rates.

3) A decrease in the number of candidates that die on the waitlist who had received an offer of an organ that was transplanted
4) An increase in utilization rate of organs from older donors.
5) An increase in utilization of organs from participants in collaborative improvement programs.
6) An increase in the utilization rate of DCD donor organs
7) An increase in the number of transplants of machine perfused organs
8) An increase in transplants performed through kidney paired donation.

Goal 2: Provide equity in access to transplants

Resource Allocation Benchmark: 30%

Core activities:

Through a consensus-driven and transparent process, the OPTN brings together a group of individuals with diverse backgrounds and professional perspectives to develop equitable allocation policies. The OPTN Board of Directors and advisory committees are comprised of transplant and donation professionals, patients, living donors, and donor and recipient family members who bring varying and unique perspectives to produce policies that are equitable across all patient populations.

UNOS research staff aggregate national OPTN data and analyze trends in transplantation, which allows for the identification of inequities among transplant patient populations.

The OPTN monitors allocation matches to ensure organ allocation policies are followed and fosters public trust in the national transplant network through public communications.

Initiatives:

1) Improve equity in transplant opportunities for multi-organ and single organ candidates.
    a) Include measures of multi-organ transplants in transplant center metrics.
2) Implement continuous distribution policy framework in all allocation policies to increase equity and provide more flexible, patient-focused allocation policies.
    a) Monitor and evaluate effectiveness of changes to allocation policies
    b) Refine allocation policies to achieve maximum effectiveness towards the goal
3) Increase the ability for allocation policies to be dynamic and incorporate changes in faster policy cycles to respond to post-implementation findings
4) Examine differences in access to transplant among different ethnic, economic, and geographic groups and develop strategies as indicated to address any identified disparities
5) Increase racial, ethnic, and professional diversity on the Board and committees to ensure a variety of perspectives are offered in the policy development process.
    a) Review current demographic data for key populations (MDs, transplant program and OPO personnel, patients, donor families, etc.)
    b) Evaluate the election process for patient and donor representatives
    c) Improve recruiting and awareness efforts with potential minority participants
    d) Increase diversity in age of board and committee members

Key metrics:

1) Increased equity in access to transplant as measured by UNOS published equity in access methodology
2) Reduction in time from policy project origination to implementation
3) The volunteer workforce will reflect the patients and professionals served by the OPTN
4) Increase the average number of individuals per cycle participating in the OPTN public comment period

Goal 3: Promote living donor and transplant recipient safety

Resource Allocation Benchmark: 10%

Core activities:

The OPTN establishes minimum membership requirements for key personnel at transplant programs, OPOs, and histocompatibility laboratories. The OPTN patient safety portal allows member programs to report potential patient safety events. UNOS conducts routine on-site audits to evaluate member compliance with OPTN policies and reviews transplant program and OPO performance including outcomes and activity levels. Through a confidential medical peer review process, the OPTN may investigate potential member institutions non-compliance with OPTN obligations and the Board of Directors may take member actions.

Initiatives:

- Enhance sharing of knowledge about safety events, near misses, and effective practices across the transplant community.

Key metrics:

1) Increase percentage of members' feedback that the OPTN MPSC is focused on improvement, as well as compliance and safety
2) Increase the number of members who respond that the peer review process is valuable in process improvement
3) On an annual basis, a minimum of 20 reported referrals sent from Member Quality to Professional Education or OPTN committees to be addressed through communications or educational offerings

Goal 4: Improve waitlisted patient, living donor, and transplant recipient outcomes

Resource Allocation Benchmark: 10%

Core activities:

UNOS aggregates national OPTN data and analyzes trends in transplantation and provides meaningful and actionable reports and tools to members that contribute to the collective knowledge of effective organ transplantation.

Initiatives:

1) Include recipient longevity in transplant center metrics.
2) Evaluate effective methods for assessing living donor outcomes.
3) Enhance transplant program tools and education in the selection and follow up of living donors.
4) Develop tools to calculate survival benefit to inform center practices, patient management, and OPTN policy development.
5) Improve patient tools for understanding the allocation process and organ acceptance strategies
6) Improve the process/management of donor information that becomes available after transplantation (blood cultures, sputum cultures, urine cultures, etc).

Key metrics:

1) A reduction in waitlist mortality.
2) An increase in 1-year graft and patient survival rates.
3) An increase in the 5-year graft and patient survival rates.

OPTN

Public Comment Proposal

Modifications to the Deceased Donor Registration (DDR) Form

OPTN Organ Procurement Organization Committee

Prepared by: Robert A. Hunter
UNOS Policy and Community Relations Department

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OPTN

Modifications to the Deceased Donor Registration (DDR) Form

Affected Policies: *N/A*
Sponsoring Committee: *Organ Procurement Organization*
Public Comment Period: *January 21, 2021 – March 23, 2021*

Executive Summary

The Deceased Donor Registration (DDR) is part of the Transplant Information Electronic Data Interchange (TIEDI®), which is part of the OPTN data entry system (UNet[sm]) for transplant centers, OPOs, and histocompatibility laboratories across the county that also includes DonorNet® and Waitlist[sm]. The DDR is a record of donor information completed for all deceased donors from whom at least one organ has been removed for the purposes of transplantation. This information is used to evaluate OPO performance, monitor potential disease transmission, and evaluate post-transplant outcomes, among other things.

In this proposal, the OPTN Organ Procurement Organization (OPO) Committee proposes changes to the DDR. These recommendations are a result of a comprehensive review of the DDR as well as the data definitions.

This proposal will promote more consistent and accurate data collection by modifying, removing, or relocating data elements. The intent of these proposed changes is to improve the quality of data and provide OPO staff with improved direction and clarity when entering deceased donor data into the DDR.

The National Organ Transplant Act of 1984 (NOTA) requires the Organ Procurement and Transplantation Network (OPTN) to "collect, analyze, and publish data concerning organ donation and transplants."[1] Organ procurement organizations (OPOs) submit data on deceased donors electronically through UNet, a secure web-based data collection system. The proposal also aligns with the Final Rule's requirement that the OPTN and Scientific Registry "[m]aintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors" and "[m]aintain records of all transplant candidates, organ donors, and transplant recipients."[2]

[1] NOTA, 42 U.S.C. § 274(b)(2)(I)
[2] 42 CFR § 121.11 (a)(1)(i)-(ii)

Background

Under the OPTN Final Rule, OPOs and transplant centers are required to submit data to the OPTN.[3] In 2006, the OPTN established the principles of data collection where institutional members must provide sufficient data to allow the OPTN to do the following[4]:

- Develop transplant, donation, and allocation policies – Deceased donor data provides information useful for developing evidence-based allocation policies.
- Determine if OPTN members are complying with policy – This ensures trust in the transplant system by using data to evaluate member compliance with OPTN policies.
- Determine member-specific performance – In collaboration with the SRTR, the OPTN is required to make information on OPO performance publically available.
- Ensure patient safety when no alternative sources of data exist – Clinical information on deceased donors can provide an understanding of potential impacts on patient outcomes and patient safety.
- Fulfill the requirements of the OPTN Final Rule.

Additionally, the OPTN Board of Directors approved the following OPTN Data Vision Statement during its December 5-6, 2016 meeting:[5]

> *The OPTN collects information in accordance with the Final Rule: 1) to characterize the population it serves; 2) to improve the allocation and utilization of organs; and 3) to develop and assess policies and processes to optimize outcomes. The overall intent is to provide value to patients, OPTN members, the organ donation/transplantation community, and the general public.*
>
> • Whenever possible, data collected in center or OPO electronic health records, and other databases should be accessible to the OPTN without the need for additional data entry.
> • Variables collected should specifically support the data uses outlined above and should be re-evaluated on a regular basis.
> • Data collected should be accurate (based on clear definitions), complete, timely, and subject to ongoing quality control audits/efforts.

The DDR is an important data collection tool for OPOs to submit information on deceased donors. *OPTN Policy 18.1: Data Submission Requirements*, requires OPOs to submit the DDR within "30 days after the donor organ disposition (feedback) form is submitted and disposition is reported for all organs." It should be noted that this requirement will change to 60 days following implementation of OPTN Board-approved data submission policy changes.[6] A copy of the DDR can be found in **Appendix A.** The sections of the DDR include:

[3] 42 CFR § 121.11
[4] "Principles of Data Collection," OPTN, accessed December 11, 2020. https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/
[5] https://optn.transplant.hrsa.gov/media/2038/board_executivesummary_201612.pdf
[6] https://optn.transplant.hrsa.gov/media/3459/modify-data-submission-policies-policy-notice.pdf

- Clinical information
- Lifestyle Factors
- Organ Recovery
- Procurement and Authorization
- Donor Information
- Organ Dispositions

The most recent substantive changes to the DDR occurred in 2010 when the Policy Oversight Committee (POC) conducted a comprehensive review of all TIEDI forms. This 2010 project was initiated in order to identify any necessary changes as part of the three-year cycle of review and approval of all OPTN forms by the Office of Management and Budget (OMB). The POC distributed these proposed changes for public comment and the OPTN Board of Directors subsequently approved the changes in November 2010.[7] The proposal resulted in changes to all TIEDI forms and the changes to the DDR included the addition of twenty-five data elements, modification of four data elements, and deletion of nine data elements.

The OPO Committee routinely reviews member questions about the data fields and data definitions that are submitted to the UNOS Research department. The number of questions reviewed during biannual in-person committee meetings has increased over the years, from two in March 2015 to seven in October 2018. The questions also varied in complexity, which led to the decision to initiate a comprehensive review of the entire data collection form. The timing of this review also corresponds with the DAC charge to review all OPTN data collection tools.

The Committee collaborated with the OPTN Data Advisory Committee (DAC) in developing this proposal. The DAC is an operating committee of the OPTN and oversees all data-related functions, including collaborating with other OPTN committees on additions, modifications, and deletions of data elements collected by the OPTN in order to improve the completeness, accuracy, and timeliness of the data.[8] The joint workgroup comprised of members from both committees provided input on the draft DAC Data Element Standard of Review Checklist shown in **Appendix B**. This draft checklist was a collaborative effort by SRTR, UNOS Research, and UNOS Information Technology staff as well as DAC members. The purpose of this checklist is to provide a tool to ensure a consistent and systematic approach to aid OPTN Committees in the assessment of data they seek to add, modify, or remove.

UNOS staff developed a data review worksheet using the checklist. Workgroup members reviewed each data element and completed the worksheet using the criteria outlined in the checklist. UNOS staff reviewed the completed worksheets to determine which information required further discussion. Workgroup members, in collaboration with SRTR and UNOS Research department staff, used their clinical expertise to develop recommendations for changes to the data elements and definitions. Additional feedback was received from the leadership of several committees, including the Ad Hoc Disease Transmission Advisory Committee, Heart Transplantation Committee, and Liver and Intestinal Organ Transplantation Committee.

[7] https://optn.transplant.hrsa.gov/media/1799/executivesummary_1110.pdf
[8] https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/

Purpose

These changes will ensure the data available to the community and the OPTN provides accurate analyses to meet the requirements in the OPTN Final Rule "that the OPTN and Scientific Registry "[m]aintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors," and "[m]aintain records of all transplant candidates, organ donors, and transplant recipients".[9]

Overview of Proposal

The Committee is proposing modifications to the DDR and the data definitions. The Committee is also seeking specific feedback on several data elements, including citizenship, donor management medications, transfusions, clinical infections confirmed by culture, cocaine and other drug use, and Chagas/TB history.

Proposed Modifications

Table 1 outlines the proposed modifications to the DDR.

Table 1: Recommended Changes to the DDR

Data Element	Recommended Changes
Home city	Add the option to enter "unknown." This is important due to situations where OPOs are unable to collect and report this information.
Home State	Add the option to enter "unknown." This is important due to situations where OPOs are unable to collect and report this information.
Home Zip code	Add the option to enter "unknown." This is important due to situations where OPOs are unable to collect and report this information.
Procurement and Authorization (section title)	Remove "Procurement and" from the title. Based on the recommendations to move "cardiac arrest since neurological event that led to declaration of death" and "date and time of pronouncement of death" to the organ recovery section, the information collected in this section focuses on authorization for donation.

[9] 42 CFR § 121.11(a)(1)(i)-(ii)

Data Element	Recommended Changes
Medical examiner/coroner	These recommendations will capture information about how the interaction with the medical examiner/coroner affects authorization for organ donation. ***Current:*** Medical examiner/coroner: • No • Yes, Medical examiner consented • Yes, Medical examiner refused consent ***Proposed changes:*** • Did the OPO notify the medical examiner/coroner? ○ Yes ○ No – skip 2 questions below If yes, did the medical examiner/coroner accept the case? ▪ Yes ▪ No If yes, were there any restrictions? • Multi-select menu of all organs
Did the patient have written documentation of their intent to be a donor?	Align with proposed changes to the death notification registration (DNR) by replacing with the following two questions. • Did patient legally document decision to be a donor? • Was authorization obtained for organ donation?
Terminal lab data	Update data definition to specify that the terminal lab values include tests performed during donor management and prior to the donor entering the OR. The intent of this change is to mitigate inconsistencies when additional lab tests are performed in the donor OR. If a lab value is unavailable, only allow “not done” option instead of N/A, not done, missing, unknown. Switch the order of serum lipase and serum amylase Update “Na” in DonorNet to align with serum sodium in the DDR

Data Element	Recommended Changes
Serology	Rename using the common terminology “infectious disease testing” and delete the separate NAT results section by incorporating NAT results into the same section since these are all infectious disease testing results. Add the word “equivocal” to the response options, as shown below, since lab results can be indeterminate (no clear negative or positive result) or equivocal (cannot be interpreted as negative or positive). For each of the tests listed, select the results from the lists (Cannot Disclose, Indeterminate/Equivocal, Negative, Not Done, Positive, or Unknown). These fields are required.
Inotropic medications at time of cross clamp	Update field label to include “or at time of withdrawal of life-sustaining medical support” in order to capture this information for donation after circulatory death (DCD) donors.
According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne transmissions	Remove “on the date of referral” to make the question clearer.

Data Element	Recommended Changes
Was this donor recovered under DCD protocols? If yes, • Controlled? • Date/time of withdrawal of support • Date/time agonal phase begins If DCD, total urine output during OR recovery phase If yes, core cooling used If yes, date/time of • Abdominal core cooling • Thoracic core cooling • Portal vein core cooling • Pulmonary artery core cooling	Remove option for an unknown response to "If Yes, controlled." The rationale is that OPOs will know whether it was a controlled or uncontrolled DCD and therefore the option of "unknown" is unnecessary. Update the field as shown below: • If Yes, Date and time agonal phase begins (systolic BP < 80mmHg or O2 sat. < 80% sustained): Remove this data element because this is difficult to collect/measure and is not used to assess kidney function during the recovery procedure. Remove "If yes," so the core cooling information is collected on both donation after brain death (DBD) and DCD donors. Replace "core cooling" with a more commonly used terminology such as perfusion or flush "Gray out" the remaining fields (abdominal, thoracic, portal vein, and pulmonary artery) if the initial response to use of core cooling is "no."
History of MI	Add this data element to DonorNet so the information can cascade to the DDR.
Was a pulmonary artery catheter placed? If yes, initial and final preoperative measurements	Update this data element to include measurements obtained by minimally invasive monitoring methods, which are becoming more common. Were advanced hemodynamic parameter data obtained? • If yes, indicate the method (pulmonary artery catheter or minimally invasive monitoring) and report one set of measurements

Data Element	Recommended Changes
Liver Biopsy: % macro vesicular fat	Align the terminology with the upcoming programming for the expedited placement of livers, which will include the collection of macrosteatosis percentage, if available. This will remain an open numeric field in both DonorNet and the DDR.
Lung (right and left) bronchoscopy	Update data definitions to specify that when multiple bronchoscopies are performed, enter the last results prior to the donor entering the operating room. Add an additional response option for "abnormal-other" results and remove "unknown if bronchoscopy performed" since OPOs will know whether a bronchoscopy was performed. Update the following responses: • No Bronchoscopy • Bronchoscopy Results normal • Bronchoscopy Results, Abnormal-other • Bronchoscopy Results, Abnormal-purulent secretions • Bronchoscopy Results, Abnormal-aspiration of foreign body • Bronchoscopy Results, Abnormal-blood • Bronchoscopy Results, Abnormal-anatomy/other lesion • Bronchoscopy Results, Unknown • ~~Unknown if bronchoscopy performed~~
Lung machine perfusion intended or performed	Delete "intended or" and only collect if actually performed since intended perfusion does not provide useful data.
If DCD, date/time organ recovered or removed from donor	Remove "If DCD" so this information is captured for both DCD and DBD donors on all organs.
Recovery team #	Change from 6-digit provider number to 4-digit OPTN center code and 3-digit OPTN center type of the transplant center team recovering the organ. This will provide more accurate data since broader distribution has increased the use of local recovery surgeons. Update data definitions to clarify that if the OPO provides the recovery team the OPO center code and center type must be entered.

Data Element	Recommended Changes
Initial flush solution and volume	Retain type of initial flush solution but remove “volume” requirement for liver and pancreas since volume is not relevant information to collect for flush solutions.
Back table flush solution and volume	Retain type of back table flush solution but remove “volume” requirement for liver and pancreas since volume is not relevant information to collect for flush solutions.

Table 2 outlines the proposed modifications to the DDR data definitions.

Table 2: Proposed Modifications to DDR Data Definitions

Data Element	Recommended Modifications to Data Definitions
First name, middle initial, last name	Update data definition to provide general direction about how to enter information when the donor identity is unknown in order to promote consistency. • Last Name: Enter the donor’s last name. **This field is required.** • First Name: Enter the donor’s first name. **This field is required.** • Middle Initial: Enter the donor’s middle initial. If the donor identity is unknown, enter the hospital-generated alias.
Weight	Update data definition to specify that the weight entered should be the weight at time of hospital admission. • Enter the weight of the donor at time of hospital admission in lbs (pounds) or kg (kilograms). This field is required. • If the donor's weight at the time of recovery is unavailable, select the reason from the status drop-down list (N/A, Not Done, Missing, Unknown). This will provide better guidance about when the patient weight is measured. This will mitigate the impact of medical treatment and donor management on weight values since fluids and medications can affect weight.

Data Element	Recommended Modifications to Data Definitions
Terminal lab data	For each of the laboratory tests enter the value, in the units indicated, from tests performed during donor management and prior to the donor entering the operating room. ~~closest to the time of recovery.~~ These fields are required. If a lab value is unavailable, select the reason from the status (ST) drop-down list (N/A, Not Done, Missing, Unknown). (List of Status codes) The intent of this change is to mitigate inconsistencies when additional lab tests are performed in the donor OR.
Lung (right and left) bronchoscopy	If a lung was recovered or transplanted, select the results of the bronchoscopy procedure from the drop-down list. If multiple bronchoscopies are performed, enter the results from the last bronchoscopy performed prior to the donor entering the operating room. If the results were abnormal, select Abnormal with the type of abnormality. If a bronchoscopy was not performed, select No Bronchoscopy. ~~If unknown, select Unknown if bronchoscopy performed~~. This field is required.
LV ejection fraction (%) and method	Provide the left ventricular ejection fraction, if known. This should be the final measurement collected prior to the donor entering the operating room. If the left ventricular ejection fraction is unavailable, select the reason from the status (ST) drop-down list (N/A, Not Done, Missing, Unknown).This field is required. Method: Select the left ventricular ejection method from the drop-down list. If a value is entered for LV ejection fraction, this field is required. (List of LV Ejection Method codes) Echo (echocardiogram) MUGA (multiple gated acquisition scan) Angiogram
Coronary angiogram	If the donor had a coronary angiogram, select Yes, Yes - normal or Yes - not normal from the list. If the donor did not have a coronary angiogram, select No. This field is required. • No • Yes, normal (no evidence of coronary artery disease) • Yes, not normal (some evidence of coronary artery disease)

Proposed Removal

Table 3 outlines the data elements the Committee proposes removing from the DDR.

Table 3: Proposed Removal from DDR

Data Element	Recommended Removal
Did the patient have written documentation of their intent to be a donor? If yes, indicate mechanisms	Remove mechanisms from DDR since OPOs collect this information and mechanisms, such as driver's license or donor card, are not used by the OPTN.
Was the authorization based solely on this documentation?	Remove from DDR, this information does not provide relevant information value about authorization for organ donation.
Did the patient express to family or others the intent to be a donor?	Remove from DDR, this information does not provide value and is difficult for OPOs to collect from family members.
Tattoos	Remove from DDR, this information does not factor into organ acceptance and is not included as a risk factor in the PHS guideline.
Cancer free interval	Remove from DDR. Reliability is a concern and dependent on historian knowledge of cancer treatment and timeframe since treatment. If a donor has a history of cancer, the transplant center will usually call the OPO for additional information.
Biopsy (heart donors only)	Remove from DDR since heart biopsies are typically not performed on deceased donors. Only two "yes" responses entered for deceased donors recovered between July 2018 - June 2019.
Recipient social security number for each organ transplanted	Remove from DDR since OPOs and transplant centers typically use the name and waitlist ID and there are concerns about the use of social security numbers as a form of identification.

Relocation

Table 4 outlines the data elements being moved to a different location/section of the DDR.

Table 4: Proposed Relocation of Data Elements

Data Element	Current Location/Section	New Location/Section
Cardiac arrest since neurological event that led to declaration of brain death If yes, duration of resuscitation	Procurement and Authorization	Organ Recovery – The procurement and authorization section is being modified to only collect information about authorization for donation.
Date and time of pronouncement of death	Procurement and Authorization	Organ Recovery – The procurement and authorization section is being modified to only collect information about authorization for donation.
NAT results	Clinical information – separate section	Recommendation: Include NAT results in the "Infectious Disease Testing" section (previously labeled "serology")
Clamp date, clamp time, clamp time zone	Organ recovery	Keep in the organ recovery section but move to the beginning of the section, potentially replacing recovery date.

Specific Feedback Requested

The Committee is requesting specific feedback on the data elements shown in **Table 5**. The Committee did not reach consensus on recommendations and therefore requests feedback from the community. Public comment feedback will determine the next steps to address recommended changes. Additionally, some changes could have policy implications and impact other systems within UNet which will require additional evaluation before finalizing recommendations.

Table 5: Specific Feedback Requested

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Recovery date	The rationale for proposing the removal of "recovery date" from the DDR is that no significant events occur between entering the OR and cross clamp that need to be captured as a data point. Additionally, if the recovery date is different from the cross-clamp date, there is a greater change for data entry errors.	Should both recovery date and cross clamp date/time be collected?

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Citizenship	Citizenship information is also collected on the transplant candidate registration (TCR), however, only the DDR allows an "unknown" option. It can be challenging for OPOs to collect citizenship information from family members when evaluating deceased donors.	Should donor citizenship still be collected on the DDR?
Donor management (Any medications administered within 24 hours of cross clamp) ○ Steroids ○ Diuretics ○ T3 ○ T4 ○ Antihypertensives ○ Vasodilators ○ DDAVP ○ Heparin ○ Arginine Vasopressin ○ Insulin ○ Other/specify	These data are currently collected as yes, no, or unknown responses and do not provide dosages or identify how long these medications were administered to the donor.	Should the list of medications be updated? Should dosages and duration be collected instead of yes, no, or unknown? Should these medications only be provided at certain time points (for example, time of extubation, initiation of agonal phase, initiation of flush) instead of within 24 hours prior to crossclamp?
Number of transfusions during terminal hospitalization	Recommendation to collect the total volume instead of the number of transfusions. Currently, number of transfusions response option include None, 1-5, 6-10, greater than 10, or unknown. Recommended changes: ○ Transfusions during terminal hospitalization? – yes or no ○ If yes, total volume	Should there be a specific timeframe for reporting transfusions during the terminal hospitalization?

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Clinical infection confirmed by culture	This data element is very broad and requires interpretation by data entry staff. Feedback from Ad Hoc Disease Transmission Advisory Committee (DTAC) leadership raised additional questions. For example, the presence of a positive culture does not always indicate an infection. The impact of positive cultures can depend on the specific type of pathogens present as well as symptoms.	Should this field be modified to capture more granular data? Currently, yes, no, unknown response options. If yes, must indicate source (blood, lung, urine, other-specify)

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Cocaine use (ever) AND continued in last six months Other drug use (ever) AND continued in last six months	The terms "abused" and "dependent on" are subjective Family members are not always aware of drug use so reliability is an issue "Other drug use" is overly broad. For example, crack, marijuana and prescription narcotics are all listed in the data definitions for this field but they have different effects on organs. Additionally, marijuana is listed as a "street drug" even though it has medicinal use and is legal in many states. There was discussion about the intent of collecting this information, which could include any of the following: • Cause of death due to drug use • Lifestyle factors that increase the risk of infectious disease transmission • Abuse/use that affect organ(s) – For example, cocaine and amphetamine use could have an impact on the heart as well as blood vessels. In order to improve data collection, the Committee proposes using language similar to the universal donor risk assessment interview questions (UDRAI).[10] OPO staff typically use this standardized document when completing the DDR.	Does the information in the proposed changes below provide more useful information on drug use than the current yes, no, and unknown response options? Ever use or take drugs, such as steroids, cocaine, heroin, amphetamines, or opioids? • Type of drug • How often and how long was it used? • When was it last used? • Route (inhaled, needles, ingested)

[10] https://www.myast.org/sites/default/files/pdfs/uniform_drai_donor_12_older.pdf

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Chagas and TB (tuberculosis) history	Not all OPOs routinely test donors for Chagas and TB. If there is a documented history of infectious disease, additional information about the diagnosis and treatment would be helpful. DTAC leadership agreed that Chagas and TB information is important but risks could be captured in another way. Such as demographic information (birthplace, long-term residency, travel outside the US) that help identify risk factors.	Should the OPTN collect additional information on Chagas and TB including specific risk factors for each in order to evaluate patient safety and transplant outcomes?
Organ recovery section	If controlled DCD, measures between withdrawal of support and (circulatory standstill or circulatory death. Provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1-minute between start of agonal phase and cardiac standstill (or cardiac death).	Should this information still be collected on the DDR? If so, how often should the systolic blood pressure, diastolic blood pressure, mean arterial pressure, and O2 saturation be reported.

Future Project

The Committee discussed the following data elements collected on the DDR, in DonorNet for allocation, and on the death notification registration (DNR): Cause of death, mechanism of death, and circumstances of death. The Committee is not seeking feedback on these data elements as part of this proposal. The Committee is recommending a separate project to address these data elements.

The available responses can lead to inconsistent entry of this information by OPOs. The categories are broad and difficult for OPO staff to match up based on the circumstances that led to the declaration of death. For example, an accidental overdose might be interpreted a number of ways by different OPOs. Additionally, these categories have been in place for many years without any significant changes. Finally, any future changes will need to be evaluated to determine the potential impact on the SRTR expected yield models.

The Committee also identified two data elements in the organ dispositions section that need to be further evaluated and updated.

- Reason code – These codes include the reason for the following:
  - Reason authorization was not requested
  - Reason authorization was not obtained

    - Reason why organ was not recovered
    - Reason organs was recovered but not for transplant
    - Reason organ was recovered for transplant but not used for a transplant
- Reason organ not transplanted
    - List of discarded codes

NOTA and Final Rule Analysis

NOTA requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants."[11] The OPTN requires OPOs to submit data on deceased donors electronically through UNet, a secure web-based data collection system, to fulfill this requirement. The Final Rule requires the OPTN and Scientific Registry to "maintain and operate an automated system for managing information and records of all transplant candidates, organ donors, and transplant recipients."[12] These modifications will ensure that the OPTN provides more accurate and better quality data on deceased donors.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

This proposal will require OPO staff to become familiar with the changes to the DDR and data definitions.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of Histocompatibility Laboratories.

Operations affecting Transplant Hospitals

This proposal is not anticipated to affect the operations of transplant hospitals.

Operations affecting the OPTN

This proposal will require programming in UNet. Feedback received on the data elements in question will be taken into consideration for final decisions on programming efforts.

This proposal will require modifications to official OPTN data currently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

[11] NOTA, 42 U.S.C. § 274(b)(2)(I)
[12] 42 CFR § 121.11(a)(1)(i)-(ii)

Potential Fiscal Impact of Proposal

OPOs

The process for completing the DDR may vary among OPOs, but staff time and potential (minimal) cost savings per case may result due to a more succinct and streamlined form. The updated form should improve the completion process for any OPO, regardless of internal workflow. This could potentially reduce administrative burden, as OPO staff will spend less time trying to interpret how the data should be entered or reaching out to the OPTN for assistance.

Minimal implementation time is necessary to educate staff and update internal workflow.

Transplant Hospitals

There is no expected impact for transplant hospitals.

Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

Preliminary estimates indicate that this will be a large effort, as over 800 hours may be needed for IT programming, communication, educational efforts, and post-implementation monitoring.

Post-implementation Monitoring

Member Compliance

This proposal will not change the current routine monitoring of OPTN members. Site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported in the DDR is consistent with source documentation.

Policy Evaluation

These data modifications will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data to UNet) and compared to an appropriate pre-implementation cohort. Summary statistics, distributions, and missingness for modified data elements *(Table 2)* will be compared pre- and post-implementation.

Conclusion

As discussed throughout the document, improvements to data collection tools are imperative to promote more consistent and accurate data collection by clarifying the data elements and updating the associated data definitions. These changes support the OPTN's task to collect transplant data according to regulatory requirements and the OPTN contract. Accurate data collection is important for

performance improvement, evaluation of transplant system performance, and assessment of how the transplant system is performing.

The proposal aligns with the Final Rule's requirement that the OPTN and Scientific Registry to "maintain and operate an automated system for managing information…..and records of all transplant candidates, organ donors, and transplant recipients."[13]

The Committee is proposing modifications, removal, and relocation of data elements. The Committee is also seeking feedback on several data elements.

[13] 42 CFR § 121.11(a)(1)(i)-(ii)

Appendix A: Deceased Donor Registration[14]

Deceased Donor Registration Worksheet

FORM APPROVED: O.M.B. NO. 0915-0157 Expiration Date: 08/31/2023

Note: These worksheets are provided to function as a guide to what data will be required in the online TIEDI® application. Currently in the worksheet, a red asterisk is displayed by fields that are required, independent of what other data may be provided. Based on data provided through the online TIEDI® application, additional fields that are dependent on responses provided in these required fields may become required as well. However, since these fields are not required in every case, they are not marked with a red asterisk.

Donor ID:

Donor Information

OPO:

Donor Hospital:

Referral Date: *

Recovered Outside the U.S.: * ○ YES ○ NO

Country:

Last Name: *

First Name: *

MI:

DOB:

Age: ○ Months ○ Years

Gender: * ○ Male ○ Female

Home City: *

State:

Zip Code:

Ethnicity/Race: *

American Indian or Alaska Native
- ☐ American Indian
- ☐ Eskimo
- ☐ Aleutian
- ☐ Alaska Indian
- ☐ American Indian or Alaska Native: Other
- ☐ American Indian or Alaska Native: Not Specified/Unknown

Asian
- ☐ Asian Indian/Indian Sub-Continent
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Vietnamese
- ☐ Asian: Other
- ☐ Asian: Not Specified/Unknown

Black or African American
- ☐ African American
- ☐ African (Continental)
- ☐ West Indian
- ☐ Haitian
- ☐ Black or African American: Other
- ☐ Black or African American: Not Specified/Unknown

Hispanic/Latino
- ☐ Mexican
- ☐ Puerto Rican (Mainland)
- ☐ Puerto Rican (Island)
- ☐ Cuban
- ☐ Hispanic/Latino: Other
- ☐ Hispanic/Latino: Not Specified/Unknown

Native Hawaiian or Other Pacific Islander
- ☐ Native Hawaiian
- ☐ Guamanian or Chamorro
- ☐ Samoan
- ☐ Native Hawaiian or Other Pacific Islander: Other
- ☐ Native Hawaiian or Other Pacific Islander: Not Specified/Unknown

White
- ☐ European Descent
- ☐ Arab or Middle Eastern
- ☐ North African (non-Black)
- ☐ White: Other
- ☐ White: Not Specified/Unknown

Citizenship: *
- ○ US Citizen
- ○ Non-US Citizen/US Resident
- ○ Non-US Citizen/Non-US Resident
- ○ Unknown

Home Country:

Cause of Death: *
- ○ ANOXIA
- ○ CEREBROVASCULAR/STROKE
- ○ HEAD TRAUMA
- ○ CNS TUMOR
- ○ OTHER SPECIFY

Specify:

[14] "Deceased Donor Registration", accessed on December 14, 2020: https://unos.org/wp-content/uploads/unos/DDR.pdf

Mechanism of Death:	DROWNING SEIZURE ASPHYXIATION ELECTRICAL STAB SIDS DEATH FROM NATURAL CAUSES DRUG INTOXICATION CARDIOVASCULAR GUNSHOT WOUND BLUNT INJURY INTRACRANIAL HEMORRHAGE/STROKE NONE OF THE ABOVE
Circumstances of Death:	MVA SUICIDE HOMICIDE CHILD-ABUSE Accident, Non-MVA DEATH FROM NATURAL CAUSES NONE OF THE ABOVE

Procurement and Authorization

Medical Examiner/Coroner:	NO YES, MEDICAL EXAMINER CONSENTED YES, MEDICAL EXAMINER REFUSED CONSENT UNKNOWN
Was the patient declared legally brain dead:	YES NO
Cardiac arrest since neurological event that led to declaration of brain death:	YES NO
If Yes, Duration of Resuscitation:	min ST=
Did the patient have written documentation of their intent to be a donor:	YES NO UNK
If yes, indicate mechanisms (check all that apply):	
Driver's license	Donor Card Donor Registry
Durable Power of Attorney / Healthcare Proxy	Advanced Directive
Other Specify	
Was the authorization based solely on this documentation	YES NO
Did the patient express to family or others the intent to be a donor:	YES NO UNK
Date and time of pronouncement of death: (Complete for brain dead and DCD donors):	Date: Time: (military time)
Date and time authorization obtained for organ donation:	Date: Time: (military time)

Clinical Information

ABO Blood Group:	
Height:	ft in cm ST=
Weight:	lbs kg ST=
Terminal Lab Data:	
Protein in Urine:	YES NO UNK
Serum Sodium:	mEq/L ST=
BUN:	mg/dl ST=
Serum Creatinine:	mg/dl ST=

Total Bilirubin:	mg/dl	ST=
SGOT/AST:	u/L	ST=
SGPT/ALT:	u/L	ST=
INR:		ST=
Hematocrit:	%	ST=
Pancreas (PA Donors Only):		
Serum Lipase:	u/L	ST=
Serum Amylase:	u/L	ST=
HbA1c:	%	ST=

Serology:

HIV Serology Results:	Positive Negative Not Done Indeterminate
HIV Ag/Ab Combo Results:	Positive Negative Not Done Indeterminate
HTLV Serology Results:	Positive Negative Not Done Indeterminate
Syphilis Serology Results:	Positive Negative Not Done Indeterminate
Anti-CMV Serology Results:	Positive Negative Not Done Indeterminate
HBsAg Serology Results:	Positive Negative Not Done Indeterminate
HBcAb Serology Results:	Positive Negative Not Done Indeterminate
HCV Serology Results:	Positive Negative Not Done Indeterminate
HBsAb Serology Results:	Positive Negative Not Done Indeterminate

EBV (VCA) (IgG) Serology Results:	Positive Negative Not Done Indeterminate
EBV (VCA) (IgM) Serology Results:	Positive Negative Not Done Indeterminate
EBNA Serology Results:	Positive Negative Not Done Indeterminate
Chagas Serology Results:	Positive Negative Not Done Indeterminate
West Nile Serology Results:	Positive Negative Not Done Indeterminate
Toxoplasma (IgG) Results:	Positive Negative Not Done Indeterminate
Strongyloides:	Positive Negative Not Done Indeterminate
NAT Results:	
HIV NAT Results:	Positive Negative Not Done Indeterminate
HBV NAT Results:	Positive Negative Not Done Indeterminate
HCV NAT Results:	Positive Negative Not Done Indeterminate
HTLV NAT Results:	Positive Negative Not Done Indeterminate

EBV (VCA) (IgG) Serology Results:	Positive Negative Not Done Indeterminate
EBV (VCA) (IgM) Serology Results:	Positive Negative Not Done Indeterminate
EBNA Serology Results:	Positive Negative Not Done Indeterminate
Chagas Serology Results:	Positive Negative Not Done Indeterminate
West Nile Serology Results:	Positive Negative Not Done Indeterminate
Toxoplasma (IgG) Results:	Positive Negative Not Done Indeterminate
Strongyloides:	Positive Negative Not Done Indeterminate
NAT Results:	
HIV NAT Results:	Positive Negative Not Done Indeterminate
HBV NAT Results:	Positive Negative Not Done Indeterminate
HCV NAT Results:	Positive Negative Not Done Indeterminate
HTLV NAT Results:	Positive Negative Not Done Indeterminate

Number of transfusions during this (terminal) hospitalization:*	NONE 1 - 5 6 - 10 GREATER THAN 10 UNKNOWN
Clinical Infection Confirmed by Culture:*	YES NO UNK
Source	
Blood	
Lung	
Urine	
Other	
Other, specify:	

Lifestyle Factors

Cigarette Use (> 20 pack years) - Ever:*	YES NO UNK
AND continued in last six months:	YES NO UNK
Cocaine Use - Ever:*	YES NO UNK
AND continued in last six months:	YES NO UNK
Other Drug Use (non - IV) - Ever:*	YES NO UNK
AND continued in last six months:	YES NO UNK
Heavy Alcohol Use (heavy= 2+ drinks/day):*	YES NO UNK
Tattoos:*	YES NO UNK
According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne disease transmission:*	YES NO
History of Diabetes:*	NO YES, 0-5 YEARS YES, 6-10 YEARS YES, >10 YEARS YES, DURATION UNKNOWN UNKNOWN
Insulin Dependent:	NO YES, 0-5 YEARS YES, 6-10 YEARS YES, >10 YEARS YES, DURATION UNKNOWN UNKNOWN
History of Hypertension:*	NO YES, 0-5 YEARS YES, 6-10 YEARS YES, >10 YEARS YES, UNKNOWN DURATION UNKNOWN
If yes, method of control:	
Diet:	YES NO UNK
Diuretics:	YES NO UNK
Other anti-hypertensive medication:	YES NO UNK

Appendix B: DAC Data Element Standard of Review Checklist

Standard/Characteristic	Criteria
Purpose and Relevancy	• What is the intent of collecting this specific data element? • Does the data element measure what it intends to measure?
Reliability	• Is the source of information objective and reliable (historian, self-report, EHR)? • Is the element designed to consistently reproduce the same results?
Definition	• Is there an industry standard for this definition? • What are the acceptable forms of documentation (or tests if lab value/results)? • What is the appropriate timeframe for data element (first, initial, serial, last, terminal, highest)? • What are the acceptable responses or response range for this data element? If a category response, can each response be mutually exclusive? • If unknown values (e.g. missing, not reported, unknown) are acceptable responses, is there adequate instruction on when those values are appropriate? • What unit of measurement? • Is this definition suitable for the variety of users providing the data (clinical vs non-clinical)?
Availability, Burden and Interoperability	• Is this element widely available for the population of patients for which it is sought to be collected? • Does this element require additional testing (e.g. invasive procedure) or measurement that is not commonly done? • Are the data easily and readily discovered by a clinical or non-clinical coordinator in EHR? • What calculations or interpretations are required before entering? • Is the data element a candidate for seamless data exchange? ○ Is there an alternative commonly available in an EHR that should be considered?
Alternative Data Sources	• Is this element already available via an external source? • If so, could the OPTN acquire this element rather than programming?
Usability and Conformity	• Is the form usable for members? • Does the arrangement / grouping of fields on the form make sense to the users? • Are the right fields on the right forms? • Is the label, as written, clear to the user with minimal explanation?

OPTN

Public Comment Proposal

Require Notification of Human Leukocyte Antigen (HLA) Typing Changes

OPTN Histocompatibility Committee

Prepared by: Courtney Jett
UNOS Policy and Community Relations Department

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Require Notification of Human Leukocyte Antigen (HLA) Typing Changes

Affected Policies: *4.4: Resolving Discrepant Donor and Recipient HLA Typing Results*
Sponsoring Committee: *Histocompatibility*
Public Comment Period: *January 21, 2021 – March 23, 2021*

Executive Summary

There is no current OPTN requirement for histocompatibility laboratories to communicate human leukocyte antigen (HLA) typing changes to transplant programs or organ procurement organizations (OPOs). Histocompatibility laboratories are required to submit the Donor Histocompatibility Form (DHF) within 30 days after procurement, but there is no requirement for direct notification to transplant programs when HLA typing differs either before or after transplant. When transplant programs are not aware of HLA typing changes, patient safety may be adversely impacted. Serious adverse events such as hyperacute rejection, graft failure, and death can occur.

Due to patient safety concerns, the OPTN Histocompatibility Committee is proposing mandatory notifications to transplant programs and OPOs when there is a critical candidate, recipient, or donor HLA typing change. The Histocompatibility Committee is working with the Organ Procurement Organization (OPO), Operations and Safety, and Kidney Committees to ensure the policy is developed with consideration for logistical implications and making sure that no candidates are disadvantaged.

The OPTN is seeking the following feedback:

- Should an automated electronic notification be included as part of this implementation?
- Should there be a policy requirement for post-procurement and pre-transplant?
- Should there be a requirement to re-execute a match run if there is a critical HLA discrepancy?
- Are the proposed notification timelines reasonable?

Background

HLA compatibility between a donor organ and a potential candidate affect how the immune system reacts to the donor organ. If an organ is transplanted into a candidate who has HLA antibodies to it, there is the potential for hyperacute rejection, graft failure, and death. OPOs and transplant programs need to know the correct HLA typing for a given candidate and donor in order to protect against adverse patient outcomes. If these discrepancies are known prior to transplant, programs can avoid potential patient safety issues. If these discrepancies are known post-transplant, programs can appropriately monitor donor-specific antibodies and adjust immunosuppressive medication as needed.

The OPTN Histocompatibility Committee reviews discrepant HLA typings at least every three months. The Committee formed a workgroup with representation from the OPO, Operations and Safety, and Kidney Committees in order to evaluate the discrepant typings reports and evaluate how communication of discrepancies should occur.

The discrepant HLA typings report includes organ donors with differing HLA information between DonorNet® and the Donor Histocompatibility Form (DHF) or when broad antigen groups are assigned due to HLA typing ambiguities. In 2019, there were 11,702 organ donors with HLA typing information in both DonorNet and the DHF, and 48 critical discrepancies in HLA typing. The Committee defines critical discrepancies as ones that are non-equivalent at one or more loci. These are discrepancies that have the potential to cause adverse patient safety events.

There have been 27 patient safety reports to the OPTN due to discrepant HLA typings between January 1, 2018 and September 1, 2020. Multiple reports specified that the transplant programs or OPOs were not contacted in a timely fashion, with a delay of between three days and three months after the discovery event.

Required double entry of HLA typing information in UNet℠ was implemented on February 27, 2020[1], and the Histocompatibility Committee developed the proposal to help address clerical errors causing discrepant HLA information. Clerical errors, however, only accounted for 30 out of 48 critical HLA typing errors in 2019. While the Committee will monitor the newly implemented policy and expects to see a reduction in discrepant HLA values due to clerical errors, there are still other causes of discrepancies that have the potential to cause hyperacute rejection, graft failure, and death in affected recipients.

The Committee and workgroup also discussed a potential requirement to re-execute a match run if there is a critical HLA discrepancy. They ultimately decided that the current policies for released organs sufficiently encompass this requirement, as they wanted OPOs to continue to manage match runs and organ offers with critical data changes during allocation. The workgroup was concerned that not all situations would require match run re-execution, and that requiring re-execution may increase cold ischemic time and other potential factors that could lead to increased organ discards.

The Committee and workgroup discussed potential requirements for discrepancies discovered post-procurement yet still pre-transplant, but there has been no evidence of discrepancies being discovered during that window within the past two years. They were hesitant to create a requirement for such an infrequent occurrence, especially as an OPO would be unlikely to know when transplant of an organ into

[1] https://optn.transplant.hrsa.gov/media/2791/histo_policynotice_201901.pdf

the recipient occurred in real time. As such, the committee and workgroup did not feel that it was practical to make a policy requirement for this situation. The Committee and workgroup also discussed whether to require notification for any HLA typing change or just for critical discrepancies. They felt that the notification requirement would not be necessary for further refinement of HLA typings, where a value would still be equivalent but would be typed at a higher resolution.

Purpose

The OPTN Histocompatibility is submitting this proposal to protect patient safety by identifying and reporting HLA discrepancies as early as possible. This proposal may affect allocation, as candidate and donor HLA typings are used for matching purposes in kidney and pancreas allocation. In addition, donor HLA typings are used to screen incompatible candidates from a match for all organs. The OPTN has the authority to propose this per the Final Rule, which states that "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[2] In addition, the OPTN Final Rule states "An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN."[3] The correct information should be available for evaluation of donor and potential recipient compatibility.

Overview of Proposal

The proposal sets forth requirements for notification of critical HLA typing discrepancies. These notifications would be required any time an HLA typing is changed to a non-equivalent value at one or more loci, regardless of the cause of the change. Any form of notification that requires acknowledgment would be acceptable, including a phone call. Notification must be followed by documentation of the correct typing.

Donor HLA Typings

If a histocompatibility lab becomes aware of a discrepancy in a donor's HLA typing from what is entered in UNet, they would be required to notify the OPO within one hour of determining the correct typing and provide documentation of the corrected typing. This documentation could include the raw HLA typing information.

After receiving the correct documentation from the histocompatibility lab, the OPO would then be required to notify all accepting transplant programs and provide documentation. This notification and documentation would be required as soon as possible, but within 12 hours. If the discrepancy is discovered prior to procurement, the OPO would also be required to notify transplant programs before procurement. The transplant program has the ability to release the organ according to *OPTN Policy 5.9: Released Organs* if it is no longer suitable for the intended candidate. If that occurs, the OPO can proceed with re-allocation according to the policies pertaining to that specific organ.

[2] 42 CFR §121.8(a).
[3] 42 CFR §121.6(a).

Candidate or Recipient HLA Typings

If a histocompatibility lab becomes aware of a discrepancy in a candidate or recipient's HLA typing from what is entered in UNet, then proposed OPTN *Policy 4.4.A.ii: Candidate and Recipient Critical HLA Discrepancies* would require them to notify the transplant program within five days of determining the correct typing and provide documentation of the corrected typing. This documentation could include the raw HLA typing information. The workgroup felt that these discrepancies did not have the same level of urgency, as they would impact post-transplant donor-specific antibody monitoring, but would not lead to rejection events.

Discrepancy Reports

The histocompatibility laboratory is required to report the reason for the discrepancy in the HLA discrepancy report within UNet. This is a current requirement under *OPTN Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results* and will continue to be required under this policy. This discrepancy report allows the Histocompatibility Committee to know which typing is correct, as well as the reason for the error. The error reason helps inform the Committee as they create and monitor applicable policies in an effort to minimize typing discrepancies. The timeline for discrepancy reporting to the OPTN has been extended from 30 to 60 days, in order to better align with the data submission requirement changes approved by the Board in December 2019.[4]

NOTA and Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the National Organ Transplantation Act, which states, "The Organ Procurement and Transplantation Network shall… (A) establish… (ii) a national system… to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs…"[5] Early communication of HLA typing changes could allow for reallocation if necessary. Reallocation due to HLA typing changes would most affect sensitized patients, with 100% CPRA patients having over a fourteen times lower offer rate per patient year than unsensitized patients.[6] The Committee also submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[7] This proposal may affect allocation, as candidate and donor HLA typings are used for matching purposes in kidney and pancreas allocation. In addition, donor HLA typings are used to screen incompatible candidates from a match.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be

[4] https://optn.transplant.hrsa.gov/media/3459/modify-data-submission-policies-policy-notice.pdf
[5] 42 USC 274(b)(2)(A)(ii).
[6] Wilk, Amber R, John Beck, and Anna Y Kucheryavaya. Two Year Evaluation of the New, National Kidney Allocation System (KAS). Richmond, VA: Organ Procurement and Transplantation Network, 2017.
[7] 42 CFR §121.8(a).

designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment**[8] because it is an evidenced-based change relying on the following evidence:
    - HLA incompatibility is the leading cause of hyperacute rejection, which leads to graft failure. Timely reporting of discrepancies allows for programs to properly assess potential deceased donors for compatibility with the intended recipient. Timely reporting also allows for proper treatment and monitoring of recipients who have already been transplanted, in order to minimize risk of rejection.
- **Is designed to avoid futile transplants**[9]**:** This proposal seeks to increase communication of HLA typing changes, in order to avoid immunologically incompatible transplants. Timely reporting of discrepancies allows for programs to properly assess potential deceased donors for compatibility with the intended recipient.
- **Is not based on a candidate's place of residence or place of listing except to the extent required by other regulatory requirements.**[10]
- **Is designed to avoid wasting organs**[11] **by** decreasing the number of organs recovered but not transplanted.
    - Early communication of HLA typing changes could allow for reallocation if necessary, so that the transplant recipient and organ are compatible.

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- **Seeks to achieve the best use of donated organs**[12] **by** ensuring organs are allocated and transplanted according to medical urgency.
- **Is designed to…promote patient access to transplantation**[13] **by** giving similarly situated candidates equitable opportunities to receive an organ offer.
- **Promotes the efficient management of organ placement**[14] **by** taking into account factors including the costs and logistics of procuring and transplanting organs.

The OPTN Final Rule also states "An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN."[15] The correct information should be available for evaluation of donor and potential recipient compatibility.

The OPTN Final Rule also requires the OPTN to consider **"whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective**

[8] 42 CFR §121.8(a)(1).
[9] Id.
[10] 42 CFR §121.8(a)(8).
[11] 42 CFR §121.8(a)(5).
[12] 42 CFR §121.8(a)(2).
[13] Id.
[14] Id.
[15] 42 CFR §121.6(a).

date of the revised policies no less favorably than they would have been treated under the previous policies."[16] It is not evident that patients would be treated less favorably under the new policy, and therefore a transition plan is unlikely to be necessary. However, the committee welcomes feedback on this issue.

Alignment with OPTN Strategic Plan[17]

Promote living donor and transplant recipient safety
Proposed changes allow histocompatibility to be accurately assessed when considering donor acceptance.

Implementation Considerations

Member and OPTN Operations

Operations affecting Histocompatibility Laboratories

Histocompatibility laboratories will need to train and ensure key personnel complete data entry for the HLA discrepancy reports. Completing the report is already a requirement under current OPTN policy.

Operations affecting Organ Procurement Organizations

OPOs will need to train staff on the requirement to notify and provide documentation to all accepting transplant programs.

Operations affecting Transplant Hospitals

Transplant hospitals will need to provide staff training on the new requirements regarding the expected notification and HLA information that will be received for reported discrepancies.

Operations affecting the OPTN

The OPTN will create educational materials to support members with the new requirements established in this proposal.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

According to recent data reviews, a minimal number (<30) of match runs per year occurred nationwide that required a significant change to HLA typing and a new match run. When an event occurs, lab and OPO communication must occur quickly. Labs currently have systems to address critical values and alert value reporting.

[16] 42 CFR §121.8(d).
[17] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

Since these are rare events, the new requirement should not have significant effect on staffing or hours. In the rare case that allocation must be re-run due to a significant HLA discrepancy, the accepting transplant center or lab may need to perform additional testing, such as prospective flow crossmatch or virtual crossmatch.

Cost savings include better patient safety and reduced risk of major discrepancy events. Implementation time is minimal, as system programming and alert messaging will be performed the OPTN.

Projected Impact on Organ Procurement Organizations

While typing change events occur in relatively small numbers, the proposed required notification could result in significant staff time and effort to notify multiple transplant centers and OPOs per case. This could also require additional staff time for reporting and verification purposes if reported post-transplant. Additionally, when a significant error is reported during allocation, there may be a need to close the match runs and reallocate which is a current practice for many OPOs.

Projected Impact on Transplant Hospitals

There is no or minimal expected impact for transplant hospitals. This proposal strives to ensure that recipients receive compatible organs and are able to be appropriately monitored post-transplant. While this would affect a small number of recipients a year, this could save significant resources on each affected patient.

Projected Impact on the OPTN

There is minimal expected impact for the OPTN, as this proposal does not require programming efforts.

Post-implementation Monitoring

Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet℠ may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[18]

This proposal will be formally evaluated at approximately 1, 2, and 3 years post- implementation. The following metrics, and any subsequently requested by the Committee, will be evaluated as data become available (appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet) and compared pre- and post-implementation:

- The number of donor and recipient discrepancies reported in UNet

[18] 42 CFR §121.8(a)(6).

- The source of these discrepancies (Donor Histocompatibility Form, Recipient Histocompatibility form, Waitlist, etc.)
- The count and percent of these discrepancies marked resolved after three months
- The reported reasons for those discrepancies that have been resolved

Conclusion

This proposal is intended to protect patient safety through required communication and documentation of discrepant HLA typing results. This proposed policy applies to candidate, recipient, and donor HLA typings. The Histocompatibility Committee and community have taken steps to minimize HLA typing discrepancies, and they need to be communicated quickly when they do occur to reduce the chance of an adverse event.

The OPTN is seeking the following feedback:

- Should an automated electronic notification be included as part of this implementation?
- Should there be a policy requirement for post-procurement and pre-transplant?
- Should there be a requirement to re-execute a match run if there is a critical HLA discrepancy?
- Are the proposed notification timelines reasonable?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

4.4 ~~Resolving~~ Critical HLA ~~Discrepant~~ Discrepancies in Candidate, Donor, and Recipient HLA Typing Results

~~Laboratories must submit donor and recipient histocompatibility forms to the OPTN after transplant according to Policy 18: Data Submission Requirements. After laboratories submit donor and recipient HLA typing results to the OPTN, the OPTN will provide a report to the laboratories including any discrepant HLA typing results.~~

~~Laboratories must resolve discrepancies within 30 days of notification of discrepant HLA typing results. The Laboratory Director or designated staff must contact the other Laboratory Director or designated staff to resolve the discrepancies. Each laboratory involved in the HLA typing discrepancy must identify and report the reason for the discrepancy to the OPTN.~~

~~The OPTN will remove all discrepant flags from HLA typing results that have been resolved. Discrepancies that have not been resolved will remain flagged. The Histocompatibility Committee will review, at least every three months, any outstanding discrepant typing recorded since the last review. The committee will use the results of these reviews to determine whether policy modifications are required.~~

For the purposes of this policy, a human leukocyte antigen (HLA) critical discrepancy is a difference among non-equivalent values, according to *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences*, at one or more loci in a candidate's, donor's, or recipient's HLA typing.

4.4.A Requirement to Notify Transplant Programs and OPOs

4.4.A.i: Donor HLA Critical Discrepancies

If a laboratory becomes aware of a critical discrepancy in a donor's HLA typing, the laboratory must notify the host OPO of the discrepancy. Notification and supporting documentation must be provided as soon as possible, but no later than one hour following the discovery of the discrepancy.

Upon receipt of documentation of the discrepancy, the OPO must do the following:

- If the discrepancy is discovered prior to procurement, the OPO must notify and provide supporting documentation to all accepting transplant programs as soon as possible, but no later than 12 hours following discovery of the discrepancy or prior to procurement, whichever occurs first.
- If the discrepancy is discovered post-procurement, the OPO must notify and provide supporting documentation to all accepting transplant programs within 12 hours following the discovery.

4.4.A.ii: Candidate and Recipient HLA Critical Discrepancies

If a laboratory discovers a critical HLA discrepancy in a candidate's or recipient's HLA typing, the laboratory must notify the listing transplant program and provide documentation of the discrepancy as soon as possible, but within 5 days following discovery of the discrepancy.

4.4.B: Requirement to Resolve Critical Discrepant Donor and Recipient HLA Typing Results

The laboratory director of ~~each~~ laboratory involved in the HLA typing discrepancy, or their designee, must identify the correct HLA typing and report the reason for the discrepancy to the OPTN within 60 days of discovery of the discrepancy.