American Society of Transplant Surgeons

Saving and improving lives with transplantation.

ASTS Responses to UNOS Proposals Open for Public Comment

March 23, 2021

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1. Modify the Deceased Donor Registration (DDR) Form

The American Society of Transplant Surgeons (ASTS) is neutral on this proposal and submits the following comments. As background, the Deceased Donor Registration (DDR) form is part of the Transplant Information Electronic Data Interchange (TIEDI®), which is part of the OPTN data entry system (UNetsm) for transplant centers, OPOs, and histocompatibility laboratories across the country that also includes DonorNet® and Waitlistsm. 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 form 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 document for consideration is included in this hyperlink: **Modify the Deceased Donor Registration (DDR) Form.**

The suggested modifications put forth are an update to the DDR information to be collected. In general, the suggested modifications are reasonable and improve the simplicity, accuracy, and precision of the donor information to be recorded. All changes align with OPTN Goals & Strategic Plan and do not appear to increase the burden on transplant centers in any way. The changes in recording will be the responsibility of OPTN information technology and OPOs to change the program and record the data elements respectively.

Specifically, the OPTN requested feedback for certain elements found in Table 5 of the document in the link.

Table 5 Questions:

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.

1. Should both recovery date and cross clamp date/time be collected? Response: It is preferable to record only cross clamp date and time to avoid confusion. Having multiple dates for procedures is frequently confusing and can have regulatory consequences for the transplant center if there are different values recorded in different places of the record. We believe this will help alleviate situations in which there could be confusion.

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.

2. Should donor citizenship still be collected on the DDR? Response: Historically, this data was used to evaluate the ratio of foreign donors to foreign nationals transplanted. The information may still be useful to monitor and analyze. It would be important to align with the International Relations Committee's current policies on transplanting foreign nationals. The question may be somewhat sensitive for the family and appear probing which may erode some trust in the process. In addition, family may not know or want to share the correct answer. It may be preferable to remove or allow a more neutral non answer option such as "prefer not to answer."

Donor management of (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.

3. 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? Response: Most of the medications mentioned are standard in the donor management bundles and do not intrinsically add much information overall. Provided dosages and specific timeframes of the medications would seem to add laborious work that would have little impact clinically but might be helpful for some donor management research. For DCD donors, administration of heparin and timing is very important but is likely to be captured elsewhere. Dosages duration and trends of Vasopressors and Ionotropes are also important to be captured elsewhere.

Number of transfusions during terminal hospitalization: The recommendation is to collect the total volume instead of the number of transfusions. Currently, the 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."

4. Should there be a specific timeframe for reporting transfusions during the terminal hospitalization? Response: Agree with recommended changes. Total volume of each product during terminal hospitalization and volume within 24 hours of procurement OR would be helpful.

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, there are yes, no, unknown response options. If yes, the responder must indicate source (blood, lung, urine, other-specify). *Response: Agree with deferring to DTAC leadership on how best to capture this. Reporting of positive cultures, site, and sensitivities (i.e., MDR or ESBL organisms) is of paramount importance to transmit to the transplant center. However, this data is difficult to make more granular in the DDR collection format. Proper interpretation by the center receiving the offer to ascertain the risk/benefit to their patient may vary quite significantly but will likely require physician interpretation of the donor's entire hospital course and events in addition to the data on the DDR.*

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 and "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.

5. 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). Response: Agree with the proposed changes where the language will lead to more granular data and also reduce some of the stigma around drug use.

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 collecting demographic information (birthplace, long-term residency, travel outside the US) that help identify risk factors.

6. 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? Response: We concur and support the recommendations of the DTAC leadership that the information to help identify risk factors for Chagas and TB should be collected and available on the DDR.

Organ recovery section discusses (if controlled DCD) measures between withdrawal of support and (circulatory standstill or circulatory death) providing 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).

7. 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? Response: Opinions around the best way to collect data on DCD donation is still somewhat organ specific and variable based on center and surgeon specific practices. We agree with the intervals of serial data collections proposed for the DDR as a minimal standard. Many centers use agonal period definition on "start of hypoxia/hypo-perfusion time" such as SBP < 80mmHg or O2 Saturation < 80%. OPOs and transplant teams frequently used specific DCD worksheets to record and analyze specific data according to their needs.

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2. Require Notification of Human Leukocyte Antigen (HLA) Typing Changes

The American Society of Transplant Surgeons (ASTS) supports this proposal with the following recommendations. We thank the OPTN Histocompatibility Committee for their work on this proposal and offer the following feedback to their questions.

Should an automated electronic notification be included as part of this implementation? Yes. It is important to notify the accepting center as soon as possible and automated electronic notification would be the first step. If the accepting center declines the organ, then a match run could be re-run with the correct Human Leukocyte Antigen (HLA).

Should there be a policy requirement for post-procurement and pre-transplant? Yes. Once procurement has occurred, while the automated electronic notification could remain the same as above, the reallocation with a new match run might cause unnecessary delays and potential organ discard. One could consider a local backup option or other expedited forms of placement to maximize organ utilization.

Should there be a requirement to re-execute a match run if there is a critical HLA discrepancy? No. If the primary accepting center has said "yes" and is willing to take accept the discrepancy, the offer should still stand. However, if the primary center declines (for the primary patient), then a re-run would be appropriate if it is pre-procurement. When after procurement, see the response above.

Are the proposed notification timelines reasonable? Yes, in most circumstances. If the error is a simple transcription error, then the timelines are reasonable. But if it is a true typing error, the timelines are not reasonable. See the following detailed comments.

HLA typing errors, whether in a donor, candidate, or recipient, are almost unpreventable. They can occur at the pre-analytic/analytic stages, for example, by the simple act of misidentification of the specimen(s). There is currently no barrier to inadvertent misidentification although universal barcoding would go a long way toward preventing it. Errors can occur at the analytic stages from production of primary HLA typing data that is incorrect or of poor quality or from misinterpretation of primary data. Even when everything else is correct, error can creep in at the interface stages between instrumentation and computerized reporting mechanisms, especially whenever there's a human involved in transcribing the data entries.

Most laboratories performing HLA typing for the OPTN have robust systems to prevent and detect typing errors. Deceased donor typing errors can be detected pre-allocation but it is more likely for them to be detected post-allocation. The lab can discover HLA typing errors

from their own internal quality control processes but it is more likely that the lab learns of a discrepancy from an external source like an OPO, an external transplant program, or from the OPTN itself through the discrepancy report or a patient safety report.

This proposal makes no mention of reporting critical HLA discrepancies through the patient safety events portal. Critical HLA discrepancies are a patient safety issue. The proposal lacks clear development and delineation of responsibilities for reporting critical HLA discrepancies as patient safety events. Specifically, what type of HLA discrepancies should be reported as patient safety events? Who should make such reports, the host OPO, the lab originating the donor report, the transplant center(s) accepting organs, or all of the above?

Are the proposed notification timelines reasonable? Donor HLA discrepancies can have trivial or more complex explanations. Clerical error is relatively easy to detect and determination of correct HLA can be made quickly. When a discrepancy results from a difference between a host OPO HLA laboratory result and an accepting transplant center's confirmatory HLA, it might take more than 12 hours to determine the "correct" donor HLA depending upon the root cause. The discrepant labs would most certainly be employing distinct test systems and instrumentation as well as different specimens: it might not be immediately clear which of two discrepant HLA was correct. By 12 hours after receiving documentation of a discrepancy, re-allocation would likely be precluded. At that juncture, it seems more important to take whatever time is necessary to make a final determination of the "correct" HLA. Ultimately, the laboratory producing the "incorrect" HLA report must discover the root cause for the discrepancy in order to put systems in place to prevent future error and this can take time, more than 12 hours.

Ultimately, we feel that the Histocompatibility Committee should take better account of the nature of the root causes for HLA discrepancies and how and by whom they were uncovered before trying to devise policy regarding timelines for notification.

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3. Clarify Multi-Organ Allocation Policy

The American Society of Transplant Surgeons (ASTS) supports this proposal in general with recommendations. We consider this an unfinished product and an insufficient guide to good OPO practice and policy. ASTS recognizes this is a complex and controversial topic and that there are no medical criteria analogous to those adopted for liver-kidney transplants that would translate for heart-kidney and lung-kidney transplants. For this reason, we believe the UNOS/OPTN should determine what that criteria should entail as soon as possible. We offer the following responses to the questions posed by the OPTN's OPO Committee:

1. Is the 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? That would seem reasonable with the development of appropriate criteria as mentioned earlier.
2. Is a lung allocation score greater than 35 an appropriate threshold for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs? Since LAS is listed near that, ASTS would recommend OPOs allocate the organs at a threshold of 40 to 45 which would be more equivalent to a heart status of 2-3.
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? ASTS agrees that 500NM would be beneficial in increasing heart-lung multi-organ transplants.

4. Do you believe all multi-organ policies should be located in the same section of the policy? ASTS agrees with that approach.

We would also advocate clarification for OPOs when there are several competing candidates or more than the available organs allocated to multiorgan candidates (e.g. a liver-kidney, a lung-kidney and a heart kidney), all meeting criteria to send the kidney with the other organ. Should there be a priority set on predicted 7-day mortality?

We thank the OPTN for the opportunity to provide comment on the proposal and thank the UNOS committees that are working on this important project. We would encourage the OPO and other committees to complete this unfinished and incomplete proposal to include medical criteria.

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4. Develop Measures for Primary Graft Dysfunction in Hearts

The American Society of Transplant Surgeons (ASTS) is neutral on this policy proposal and submits the following comments. While the ASTS agrees overall with the intent of collecting data regarding Primary Graft Dysfunction (PGD), we have concerns with the data elements as the committee proposes. For example, Primary Graft Dysfunction/LV Dysfunction/RV Dysfunction are all Yes/No questions. What is absolutely needed is a crisp and robust definition of when a program makes those responses. The definition must be clear with low inference for data entry and abstraction. In Appendix A, the various definitions for PGD LV and PGD RV are stated. Presently, this definition is not specific enough and is open to interpretation by practitioners and transplant programs.

We have concerns about data collection and they include the following. As to capturing data on support device(s) and what device/methods of use and duration of use, we agree but see the need for well-delineated definitions and specifics. In addition, we have several questions about potential quantitative elements that are proposed. The proposal states that there are multiple time points at which the data will need to be captured. Are all considered required? One should recognize that this may prove to be a significant data burden on transplant centers.

As examples, the committee requests an LVEF to be documented. Do they want to specify modality (e.g. only with TTE/TEE)? Is post-op cardiac cath acceptable? Some official echocardiogram reports will give a range of EF (e.g. 30-40%). If so, should the data abstractor pick the lower number, the higher number, or the middle of the range? Alternatively, instead of an integer #, the committee could ask for categories (e.g. >60%, 50-60%, 40-50%, 30-40%, <30%). The committee should consider how the data field would be constructed such that data abstraction and data entry will be simplified and made as accurate as possible.

Regarding RA and PA pressure measurements, are only direct measurements to be included via a PA catheter/right heart catheterization? Will an estimated PA pressure by echocardiogram be considered an acceptable method and suffice? If so, will the methodology used be a recorded field?

As far as cardiac output is concerned, will the committee specify methodology? Is echocardiographic estimation adequate? What about thermodilution and Fick? Will the committee allow different methods, and will the method be recorded?

With regard to Inotropes, this in particular seems like a high intensity variable that may not produce meaningful data. The committee should consider requiring the minimal data needed to document adequate use of pressors to support the diagnosis of PGD, but not more granular data beyond that.

In closing, ASTS offers the following feedback to the OPTN Heart Transplantation Committee's questions. 1) We believe the Committee has suggested reasonable elements and does not recommend adding others at this time. 2) There should be a focus on both moderate and severe PGD. 3) We agree information should be collected on donors to include: EF and (if available) right atrial pressure, pulmonary artery pressures, and cardiac output which may not have to be a required data field. 4) How many hours after transplant should data collection occur? One suggestion is at 0, 12, 24, 48, and 72 hours and including discrete data elements as on page 6. We may suggest that the committee be consistent with the ISHLT definition and remain consistent with, or at least be cognizant of other societal guidelines (e.g. lung PGG which is now defined using 72-hour data). 5) As to the challenges programs face in collecting data, the committee should consider how transplant programs would manage the extra data abstraction and collection requirements, and be as parsimonious as possible to achieve the stated goals. 6) We agree the TRR is likely the best way to collect the data. 7) ASTS recommends using standard definitions with discrete data elements to ensure consistency in data collection across programs.

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5. Update Transplant Program Key Personnel Training and Experience Requirements

The American Society of Transplant Surgeons (ASTS) opposes the policy proposal as written but supports the concept overall and respectfully submits the following comments with regard to training and experience requirements for Primary Transplant Surgeons and Primary Transplant Physicians. We recommend the OPTN partner with ASTS to develop criteria focused on simplifying the certification process for foreign trained surgeons seeking to serve in the Primary Transplant Surgeon or Program Director role. Upon review of "common requirements," we believe: **Requirement 1D** still uses the term "on site" which remains vague and ambiguous (see more discussion below), **Requirement 2** requires board certification which will certainly exclude many foreign trained professionals, and **Requirement 3** is poorly written and is assumed to mean that a letter must be submitted endorsing the candidate. The requirement for "honesty and integrity" is too vague and is subject to broad interpretation.

With regard to "on site," ASTS agrees with the MPSC that this is a cumbersome and difficult designation that cannot be fulfilled in a literal sense by any one individual. The use of the phrase "on site" seems to imply the surgeon needs to be in-house. We would recommend removing the phrase and providing more clarity. The obligation of the Primary Surgeon/Physician should be to ensure that the program meets all OPTN regulations, complies with all regulations, maintains 24/7/365 coverage of the program by competent surgeons and physicians, and is available should questions arise. In addition, the Primary Surgeon/Physician should be able to designate a surrogate to cover these duties should the Primary Surgeon/Physician be temporarily unavailable to perform these duties in instances of a personal health crisis, leave of absence, or extended vacation.

We have no objections to the proposal specifically regarding Board Certification, letters of reference and recommendation, and the personal letter of qualification.

The OPTN Orientation curriculum may be a useful and helpful concept, but since this has not been developed and the product is not available to assess, including this requirement is premature and should be eliminated from this revision. It can be added later once developed and vetted.

Overall, the “Conditional Pathway” is a good idea. The area of weakness is the establishment of a mentorship/consulting agreement with another Primary Surgeon/Physician from a separate transplant program that would submit progress reports. This puts the conditional program in a difficult position and relies exclusively on the good will of the separate program to perform its duties. If a competing program decides to issue a negative report, is this to be believed and/or scrutinized? Such a report could reduce the clinical activity of the conditional program and benefit the supervising program. Further, this relies on busy and overworked Surgeons and Physicians to mentor and supervise a program other than their own. We propose that the spirit of this endeavor be retained but that the mentorship/consulting agreement take place at the level of UNOS, perhaps with the MPSC, to monitor compliance and outcomes.

The proposed changes to primary transplant surgeon requirements, in general, address the weakness of the requirement involving participation on preoperative care, transplant candidate selection, and post-operative care. The 10-year time frame for experience is not based on any evidence that we are aware of and is instead, a randomly round number of years of experience. We remain neutral on such a designation until further evidence is presented supporting that number. Selecting the number of transplants performed and the number of procurements performed will be equally difficult, random, and subject to debate. Clearly, the extremes are obvious in terms of experience or lack thereof. Where the line is drawn in terms of minimal experience is what is important and proposed for the next phase of work.

The proposed changes to primary transplant physician requirements are again mostly an improvement. We feel strongly that the requirement for a transplant physician to attend one transplant procurement and transplant procedure is unnecessary. Physicians have long provided outstanding care for peri-surgical patients without watching the actual operation. There are countless examples in all areas of medicine. This presents an unnecessary burden on a physician to take time away from patient care to observe these surgical procedures. It does not make them a better Transplant Physician. Indeed alternatives are available if the MPSC really feels that this adds to their competency. For example, the OPTN could establish a video library of a multiorgan procurement and transplant procedures and require that the physician watch these videos.

We agree with the MPSC that foreign equivalency to board certification is an important pathway; yet a difficult one. We disagree with the option that the individual should be required to complete a US based fellowship, however it would be important to have some guarantee that they have worked and/or trained in US based programs for some time with an attestation from supervisors of those programs. We would support the last option as the most comprehensive and fair mechanism to achieve foreign equivalency. For both board certification and experience, ASTS recommends using a similar process to the alternative pathways for predominately pediatric programs. It would require 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 the MPSC subcommittee.

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6. Calculate Median MELD at Transplant Around the Donor Hospital and Update Sorting within Liver Allocation

The American Society of Transplant Surgeons (ASTS) generally supports this proposal with the following concerns. The proposed system may place HCC patients at a disadvantage if priority is given to patients with a calculated MELD score over those with a MELD exception score. We recognize that HCC patients have a lower drop-out rate compared to non HCC biological MELD. ASTS, however, remains concerned that patients with MELD exception scores would likely have to wait even longer than they do under the current system, since it can take up to 6 months to obtain an exception score.

Also under the proposed system, a patient's MELD score would change based on the donor location. This may have the unintended consequence of building complexities into the system that could be overwhelming for patients and their caretakers. ASTS recommends the OPTN use a standard adjustment score across the board instead of calculating an adjustment score.

We suggest the OPTN review the policy in one year and cap the median meld at -3 of 28 and refrain from sharing for an exception on the first run when using the 50NM circle.

To the OPTN's Liver and Intestinal Organ Transplantation Committee's request for feedback, ASTS recommends:

1. What is the minimum number of transplant programs and transplants needed to calculate MMaT, as well as the use of only transplant programs that have performed a qualifying transplant? As suggested in the proposal, MMaT should be calculated at 250NM from the donor hospital. The number of transplant programs will be irrelevant.

2. MMaT calculation exclusions, update schedule, and cohort timeframe should be updated more frequently, in the realm of every three months.

3. On the proposal to calculate MMaT for donor hospitals in Alaska, we suggest the OPTN continue using the Seattle-Tacoma International Airport (Sea-Tac) as a point of reference for organ allocation.

4. On the proposed sorting approach, specifically ranking candidates with a calculated MELD or PELD score ahead of exception candidates with the same score and blood type compatibility, we believe candidates with a calculated PELD score should be ranked 1st, followed by those with a calculated MELD score, then by PELD exceptions, and then by MELD exceptions.

5. There should be no difference regarding the distinction between approved vs. assigned exceptions policy.

6. On requesting score adjustments as opposed to specific scores and if that change will be feasible for transplant programs, score adjustments would be preferred.

7. Should a 150NM circle be used to calculate the MMaT for donor hospitals or should a different circle be utilized? ASTS recommends using a 250NM circle.

8. We agree with the plan to increase the geographic basis used to calculate MMaT by 50NM increments when the minimum cohort size is not met.

9. ASTS recommends the minimum exception score should be 15, however the committee needs to determine what the equivalency of MELD 15 is for MELD-Na.

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7. 2021-2024 OPTN Strategic Plan

The American Society of Transplant Surgeons (ASTS) supports this proposal with revisions outlined below. The ASTS appreciates the thoughtful strategic plan proposed by the OPTN and finds that the goals are appropriate and reasonably weighted. However, the initiatives to reach the stated goals do not place sufficient effort on eliminating crucial barriers experienced by transplant centers to improve access, safety, and outcomes around transplantation. Therefore we propose 8 additional initiatives (and associated metrics) that better align with the overall goals of the OPTN Strategic Plan and that we believe will be more impactful for transplant recipients and donors.

The OPTN Board of Directors Executive Committee requests feedback on:

1. Do you agree with the Board's proposed areas of strategic focus for the 2021-2024 plan?
   - **A. Goal 1: Increase the Number of Transplants**
     1) Performance Metrics (increase from 1-2 to comprehensive dashboard)
        a) *New Initiative #1:* **Eliminate current performance metrics that discourage use of marginal organs for transplantation.** Current approaches to evaluate center performance discourage liberal organ acceptance practices. Although the proposed OPTN Plan positively calls for a dashboard of quality metrics to reflect comprehensive outcomes, this initiative does not go far enough to impact organ acceptance. Transplant center star ratings based on patient and graft survival should be eliminated. Replacement ratings available to the public should be designed to meet patient informational needs, such as describing outcomes relative to the alternative treatment (i.e. dialysis in the case of kidney transplantation). Outcome triggers for MPSC performance review of transplant centers should not grade transplant centers on a curve.
        b) *New Initiative #2:* **Develop new transplant center, OPO and, system performance metrics that are congruent and encourage use of higher risk organs.** Transplant center quality expectation should be based on a minimal floor for graft and patient survival that encourages increased utilization of organs at risk of discard. The current one-year graft and patient survival rates are currently very high and it is not reasonable or realistic to expect a continuous increase, nor are they the main metrics upon which we

should be focused that best describe success in transplantation. OPO centric metrics should reflect parameters that are directly under their control.

c) *New Initiative #3:* **Ensure sufficient stakeholder participation in deliberations regarding performance metrics** (OPO, transplant center and system metrics) **to avoid the adoption of metrics that conflict with Goal 1 of increasing the number of transplants.** ASTS recognizes the complexity of developing OPO, transplant performance and systems metrics. The ASTS "White Paper on Optimization of Transplant Center Assessment" outlines the complexity, issues, and recommendations for a successful approach to this endeavor that will facilitate affirmation of new metrics by the transplant community. A key principle of the approach to this goal is to engage a broad enough group of stakeholders beyond UNOS committee members to ensure sufficient deliberation and consideration of unintended consequences to avoid metrics that conflict with Goal 1 of increasing the number of transplants.

2) Pursue policies and system tools that promote system efficiency and increase organ utilization. We generally agree with the intent of initiatives, however 2) a-f we recommend that 2f should be integrated into a new overarching initiative that receives higher priority than 2a-e and the addition of:

a) We recommend integration of 2f into a new overarching initiative *New Initiative #4:* **Enhance the Efficiency and Quality of Organs Procured for Transplant** through the establishment of innovations such as organ recovery centers and collaboratives focused on best practices for organ recovery (including higher risk organs). ASTS leadership initiated a new collaborative entitled the Organ Recovery Collaborative Network (ORCN) taskforce that engages a broad group of stakeholders and is designed to enhance local recovery, reduce team travel, and standardize best practices for organ recovery and transport. Thus, we recommend that the OPTN continue to engage with ORCN as part of new initiative #4.

b) *New Initiative #5:* **Optimize Organ Transportation Efficiency.** Transportation issues result in prolonged cold ischemia time and subsequent organ refusals. We recommend the addition of the following key initiative for Goal 1. We agree with the focus on efficiency as part of Goal 1 and recommend that the OPTN focus on transportation efficiency to minimize CIT. With the expected increase in transportation of organs, it is important to maximize transportation efficiency and minimize CIT which will optimize utilization and increase the number of transplants. OPTN increased engagement with transportation arrangements to facilitate more efficient transport of organs would benefit the transplant community. In addition, we recommend tracking organ transport data, including costs to further our understanding of this critical barrier.

c) *New Initiative #6:* **Enhance the Efficiency of Placing Higher Risk Organs.** Placement of organs at high risk for discard is inefficient in our current allocation system, translating to time lost and organ discard or patient morbidity. There should be a dedicated focus on alternative allocation that allows faster placement of organs at risk for discard and policies for local back-up that minimize cold time.

d) Increase use of DCD organs: we agree with this initiative but recommend integrating this within the new initiative #4 (see 2a above).

e) Review policies to determine whether future changes will be necessary to encourage or facilitate emerging organ perfusion technologies: we agree with

this initiative and recommend integrating this initiative within the new broader initiative #4 (see 2a above).

f) Enhance the effectiveness of paired living donation programs: we agree.

Goal 1 **Key Metrics** are appropriate and will be enhanced by adoption of the new initiatives proposed above.

B. Goal 2: Provide Equity in Access to Transplants

An initiative for this goal in the Plan is to implement a continuous distribution policy framework in all allocation policies to increase equity and provide more flexible, patient-focused allocation policies. However, the impact of socioeconomic status (SES) in transplant access as a result of current and future intended allocation remains incomplete, since previous models measured only individual surrogates of SES like urbanity, payment status, and income by zip code. To ensure that all underserved communities have equitable access to transplantation, we recommend a more comprehensive analysis of SES factors in organ access, such as by using the cumulative community risk score as indicated below.

1) Improve equity in transplant opportunities for multi-organ and single organ candidates: we recommend promoting research towards this initiative to better define the optimal clinical indicators of need for multi-organ transplant and optimal timing of multi-organ transplantation (concurrent, sequential).
2) Implement continuous distribution policymaking framework: we recommend a more comprehensive analysis of SES factors in organ access, such as by using the cumulative community risk score. We also recommend serial assessment of the impact of continuous distribution policy especially upon small transplant center viability, access to transplant for patients who live in rural areas or communities that are geographically distanced from a transplant center. While the intent of continuous distribution is to enhance equity, there may be unintended consequences on certain populations who are benefited by the access to smaller transplant centers closer to their community.
3) Increase the ability for allocation policies to be dynamic and incorporate changes in faster policy cycles to respond to post-implementation findings. Agree.
4) Examine differences in access to transplant among different ethnic, economic, and geographic groups and develop strategies as indicated to address any identified disparities. Agree and we recommend a more comprehensive analysis of SES factors in organ access, such as by inclusion of the cumulative community risk score.
5) Ensure diversity in the decision makers on the OPTN Board and committees: we agree with the goal and initiatives to diversify OPTN governance and decision makers.

Goal 2 **Key Metrics** are appropriate.

C. Goal 3: Promote Living Donor and Transplant Recipient Safety

1) Educational and collaborative efforts to share best practices: we agree with efforts to promote education and collaboration.
2) We recommend adding a new Initiative *New Initiative #7:* **Enhance public education about the safeguards and safety of living donation (including kidney paired donation)** in order to encourage more living donor transplants. In

addition there should be a focused effort for public education on recipient safety and improved outcomes with living donation.

3) We recommend adding a new Initiative *New Initiative #8:* **Enhance public education about resources to minimize financial barriers to living donation (NLDAC)** in order to encourage more living donor transplants.

Key Metrics for Goal 3 are appropriate. We recommend adding two new key metrics associated with the recommended new initiatives #7 and #8 above.
Add the key metrics:

1) "Promote education to increase the number of living donor transplants performed annually."
2) "Promote education to increase applications to NLDAC for support of living donors."

D. Goal 4: Improve Waitlisted Patient, Living Donor and Transplant Recipient Outcomes

1) We recommend elimination of the initiative to "Include recipient longevity in transplant center metrics." While recipient longevity is desirable, the transplant center does not have influence on factors contributing to longevity including recipient genetics, risky behaviors, socioeconomic circumstances, or geographic mobility, transfer of care to other centers or failure to comply with transplant center follow-up.
2) We recommend revision (in parentheses) of this initiative to state…Evaluate effective methods for assessing living donor outcomes (without increasing data collection burden on the transplant center. We recommend that the OPTN take the lead in collecting living donor outcomes through centralized on-line platforms).
3) We recommend revision (in parentheses) (of this initiative to state) Enhance (the development of OPTN managed) tools and education in the selection and follow-up of living donors. (We recommend revising this initiative so that the OPTN (not the transplant center) takes the lead in the development of tools and collection of data on living donor).
4) Develop tools to calculate the survival benefit to inform center practices, patient management and OPTN policy development. We agree.
5) Improve patient tools for understanding the allocation process and organ acceptance strategies. We agree.
6) Improve the process/management of donor information that becomes available after transplantation (blood cultures, sputum cultures, urine cultures etc.) We agree.

Goal 4 Key metric to 1) reduce waitlist mortality is appropriate. We recommend the key metrics 2) and 3) to increase 1 and 5 year graft and patient survival rates respectively be removed. The 1-year graft survival rate for some organs are already extraordinarily high that it is not reasonable or realistic to establish this as an initiative. Instead, resources to support research grants investigating the causes of chronic rejection should be allocated and communicated as "Request for Applications" to the transplant community. Until the biologic and other factors responsible for chronic rejection are identified and clinical approaches can be developed, it is not reasonable to establish a metric of increased 5-year graft and patient survival.

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?
    1) See comments above for Goal 1 regarding the addition of new initiatives 1a-c, 2a-c. Resource re-allocation will be necessary to address new initiative to enhance Organ Transportation Efficiency. Yes resource allocation benchmarks will require modification (increase resource allocation to Goal 1 from 50% to 60% and decrease resource allocation for Goal 2 from 30% to 20%) to accommodate addition of new initiatives in Goal 1 which are likely to require additional personnel and development of tools.
    2) Goal 2 recommendations include revisions to the proposed goals and likely do not need change in resource allocation.
    3) Goal 3 recommendations are to prioritize the proposed two new initiatives that promote living donor and transplant recipient safety through a) focused effort on public education about the safeguards and safety of living donation (including kidney paired donation) in order to encourage more living donor transplants, b) focused effort for public education on recipient safety and improved outcomes with living donation and c) focused effort on public education about resources to minimize financial barriers to living donation (NLDAC).
    4) Goal 4 recommendations include removal of one proposed initiative and revisions of other proposed initiatives.
    5) A change in resource allocation for Goal 3 and Goal 4 is not needed.

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?
   See above comments in Goal 4 that Initiative 1 "include recipient longevity in transplant center metrics" should be removed from the strategic plan and discontinued permanently.

4. Are the stated performance metrics sufficient, measurable, and specific?
    A. Goal 1 Metrics: Yes
    B. Goal 2 Metrics: Yes
    C. Goal 3 Metrics: We recommend revision to add metrics for the additional initiatives of increasing public education about living donor safety and recipient safety, improved outcomes with living donation, and availability of NLDAC resources for living donors. <u>Add the key metrics</u>:
        1) "Promote education to increase the number of living donor transplants performed annually."
        2) "Promote education to increase applications to NLDAC for support of living donors."
    D. Goal 4 Metrics: We recommend revision.
        1) Goal 4 Key metric to 1) reduce waitlist mortality is appropriate.
        2) We recommend removal of the following two key metrics 2) increase 1- and 5-year graft and patient survival rates respectively. The 1-year graft survival rate for some organs are already extraordinarily high that it is not reasonable or realistic to establish this as an initiative. Until the biologic and other factors responsible for chronic rejection are identified, it is not reasonable to establish a metric of increased 5-year graft and patient survival. Instead, OPTN resources to support research grants investigating the causes of chronic rejection and late graft losses should be allocated and communicated as "Request for Applications" to the transplant community.

Add the metric:

a) Increase research funding that will enhance innovations to increase the longevity of transplanted organs.

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8. Update National Liver Review Board Guidance Documents and Policy Clarification

The American Society of Transplant Surgeons (ASTS) appreciates the OPTN Liver & Intestinal Organ Transplantation Committee's review of the NLRB process to improve guidance. The policy changes will serve to increase the number of patients with End-Stage Liver Disease (ESLD) who are eligible for an exception via the NLRB. We support the policy proposal overall with the following clarifications:

1. On guidance for growth failure and nutritional insufficiency: These are not adequately accounted for in the current PELD calculation and remain an important risk factor for poor waitlist outcomes. The clarifications remove the age criteria of <1 year to remove disadvantages for infants and clearly define how to calculate z-scores and anthropometric scores for malnutrition in pediatric patients. Overall, the proposed changes in the guidance would provide improved access to exception for a select group of vulnerable pediatric candidates for whom PELD scores do not fully predict wait-list drop out or mortality.

2. On pediatric guidelines: PELD and MELD scores are good discriminators of death without a transplant for many pediatric patients. However, for some patients, complications of liver disease, and not the degree of liver dysfunction, determine the need for liver transplant. Statuses and PELD/MELD scores do not reflect these complications, which have an increased risk of mortality without access to a timely transplant. In general, NLRB reviewers should be more considerate in approving PELD/MELD exceptions for children with portal hypertension complications. We believe that preventable pediatric waitlist mortality should be eliminated based on our overall commitment to this vulnerable population and fairness.

3. On addition of guidance for candidates admitted with ascites requiring IV diuretic therapy or complications of portal hypertension (ascites and GI bleeding): The proposal seeks to define the specifics of these complications more clearly for patients to qualify for PELD exceptions. The ASTS supports clarification efforts to standardize scenarios for children to get additional PELD points and suggest these could be honed further.

4. On Neuroendocrine Tumor (NET) guidance: New literature supports removal of the arbitrary age limit to improve equity and access.

5. On guidance for candidates with PSC: The policy specifies that patients must have had two hospital admissions with bacteremia or septic shock within a year. While this may help stratify this population, it may be helpful to assign a specific score to these higher risk patients. We suggest identification of a standard MELD exception score across the country (MMAT-3 or other).

6. On hilar cholangiocarcinoma standardized exception criteria: We support the proposed criteria which is in line with standard practice and would reduce the number of NLRB

applications. However, we suggest the OPTN consider the diagnosis of cholangiocarcinoma to be based on positive cytology only.

7. On metabolic liver disease: This policy clarification opens up rare metabolic diseases to exception appeals but it would be too exhaustive to list every rare metabolic syndrome that exists. Hence, centers that request this appeal must submit literature to support how transplant would ameliorate this rare liver condition.

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9. Revise General Considerations in Assessment for Transplant Candidacy

The American Society of Transplant Surgeons (ASTS) applauds the OPTN Ethics Committee for addressing the use of non-clinical considerations in transplant candidate assessment and supports this proposal with recommendations. ASTS believes that it is critical to ensure that transplant candidate assessment criteria do not discriminate among potential candidates based on race, ethnic origin, socio-economic status, gender, and other non-clinical factors that have the potential to have a significant discriminatory impact. We also recognize that the use of non-medical criteria may compound the effect of other health care disparities that result in under-referral of minority and lower income patients for transplant evaluation.

We support the OPTN position as set forth in the White Paper entitled*, General Considerations in Assessment for Transplant Candidacy,* which makes it clear that:

1. Repeat transplantation, incarceration status, immigration status, and social support should not be considered as a single criteria in determining whether a potential candidate should be waitlisted.

2. Age and “potentially injurious behaviors” alone should not disqualify a potential candidate from being waitlisted.

3. A “history of consistent and documented treatment non-adherence” may be considered so long as any mitigating factors beyond the control of the potential candidate are given full consideration

We would recommend that the White Paper be modified to specifically address discrimination based on disability. Along these lines we urge that the White Paper explicitly state that a potential candidate’s disability alone should not disqualify him or her from being waitlisted. We believe it may be helpful for the White Paper to include a discussion of the legal and moral ramifications of considering disability as a factor in waitlist determinations.

ASTS looks forward to the finalization of the White Paper and plans to urge Transplant Centers to examine their candidate assessment policies to ensure that the White Paper recommendations are implemented in clinical practice expeditiously.
