The AST Board of Directors approved the following responses to the OPTN/UNOS Spring Public Comment period. All responses were developed after review of feedback from the Society's Communities of Practice and Policy Committee.

Proposal Title: Modifications to Released KI and PA Policy (OPO Committee)

Society Response:
Given the removal of DSA from kidney and pancreas allocation that is set to be enacted December 2020, The American Society of Transplantation appreciates the need to codify in policy, a mechanism for reallocation of kidney and pancreas organs that were originally accepted and then released by the accepting center.

While generally supportive of the need for reallocation policy that avoids inefficiencies and added complexities, some AST constituencies did have questions and concerns relating to unintended consequences of this proposal on the transplant community as it is currently written.

- If the opportunity for local back up is removed, will this result in greater non-utilization of organs and longer CITs? We recognize that the monitoring plan proposed will be addressing non-utilized (discards) organs. We suggest that consideration be given to adding CITs and DGF rates to the monitoring plan.
- We assume responsibility for transporting the organ for this re-allocation lies with the host OPO. Can the OPO Committee confirm this?
- Similarly, who will pay for the re-allocation transportation? Does this become an increase to the SAC (Standard Acquisition Charge) paid by the accepting center to the OPO? This may be a possible disincentive to acceptance of a reallocated organ.

Specific Feedback requested by the OPO Committee is below:

Do you agree with the host OPO retaining responsibility for reallocation instead of delegating to the OPO in the DSA of the transplant program that originally accepted the organ?
Yes. The host OPO has the incentive to place the organ, has more intimate knowledge of the donor, the donor anatomy, etc. It would also simplify post-transplant reporting such as cultures, etc.

Do you agree with a reallocation circle of 250 NM around the transplant program with proximity points inside and outside the circle?
The concept of using the transplant program and not the donor hospital is given that this will have the potential to reduce additional ischemia time and cost associated with transporting organs across great distances. With that in mind, 250 NM may be too large of an area, particularly with pancreata. It is somewhat dependent upon how many transplant centers are in the circle and how much ischemic time the organ(s) had incurred at the time of the release. A smaller circle (150 NM) may be more practical.

What operational challenges would the new system incur for you? Specifically, what are the operational challenges related to having new "backup" match runs generated that include offers already screened off?
AST constituencies were perplexed as to why it would be prohibitively difficult to program refusal codes. It would be important, during reallocation, to not offer the organ to a center that had already turned down for a given recipient.

In addition to the host OPO being able to continue down the original match run or run a new match run around the transplant program that released the organ, does a third option need to be identified in policy for situations in which it would be appropriate to allow center backup? For example, a high kidney donor profile index (KDPI) kidney placed beyond 250 NM.

Admittedly, center back-up may be problematic in that some may consider the potential for “gaming the system” however, for high KDPI kidneys or pancreata with substantial ischemic time, it may be a reasonable alternative to minimize the risk of organ non-utilization.

Do you have concerns about cross matching under the proposed solution, or anticipate more use of virtual cross matching?
Virtual cross-matching is helpful in initial acceptance and heart, liver, and lung transplants are routing done with retrospective crossmatches (or for livers, no crossmatch at all) but there is concern among some AST constituencies that not many centers will accept a kidney or pancreas without the availability of donor specimens for an actual crossmatch, even if it is retrospective given that the risks associated with an unknown positive cross match.

Do you agree it is appropriate having the same solution for kidney and pancreas reallocation?
As most pancreata are allocated with a kidney, this approach makes sense. The caveat is related to the solitary kidney being considered similar to a kidney pancreas or pancreas alone, given that the kidney can tolerate a longer cold ischemia time. We suggest consideration and would support thresholds which would be different for solitary kidneys (KPDI) than kidney pancreas and pancreas which would trigger local back up to improve likelihood of organ utilization.

Proposal Title: Socioeconomic Status and Access to Transplantation (Minority Affairs)

Society Response:
The American Society of Transplantation constituencies and leadership have carefully considered this proposal from the OPTN Minority Affairs Committee (MAC) to add annual household income and household size fields to the Transplant Candidate Registration Form (TCR). Not unexpectedly, no consensus among AST membership was achieved. The American Society of Transplantation appreciates the intent of this proposal and agrees that lower socioeconomic status (SES) has potential negative impacts on access to the waitlist, access to living donation and post-transplant outcomes. Given that inequities in transplantation have been – and continue to be – widespread at all phases of the care continuum, efforts to capture meaningful metrics that attend to these inequities are essential. We commend the Minority Affairs Committee for offering this proposal for public comment. That said, some membership found concerns with the proposal as written.

The following comments (supportive and not supportive) from the AST are offered to the OPTN MAC for their deliberations going forward recognizing that the lack of consensus within the AST membership likely mirrors a lack of consensus regarding this proposal nationwide among the public and the transplant community.

- Pre-transplant collection of annual household income and documentation by social workers and finance specialists in the electronic medical record, while perhaps being performed at some centers, is not a component of "routine practice" nationwide. While all candidates have a social work and financial review, these evaluations relate to assessment of adequate insurance and resources to cover transplant and immunosuppression, and the availability of social support to enable compliance with appointments and posttransplant care. There is no standard practice or mandate with regard to documenting household income in any medical record.
- Complying with this policy mandate would require a change in practice without a well-grounded justification. While more granular income information may prove valuable, an interest in the impact of supplying additional information is more a question for research than national policy mandate.
- With regard to patient comfort in supplying household income information, there is recent experience in HRSA-supported SRTR Living Donor Collective pilot. This effort to construct a national living donor registry began with a *pilot program at 10 transplant centers, with part of the goal of the pilot to assess the feasibility of data collection (Am J Transplant* 2017;17(12):3040-3048. PMID: 28520316). The baseline instrument included a question on household income with well-intentioned purpose of helping identify candidates who may qualify for grants such as support from the National Living Donor Assistance Center (NLDAC). After two years of experience, the widespread feedback was that patients were commonly uncomfortable with this question and the most common response was "declined to answer".
- The OPTN MAC rationale for this proposal, as written lack sufficiently robust rationale for the need for patient -level household income collection, combined with an inadequate appreciation of the implications of adding this data collection requirement for transplant programs and patients
- Alternative sources of information, such as US Census block group data would include information on household income but also additional constructs such as neighborhood property level, median property value, household crowding, education and employment. These are establish indices for converting these publicly available data to measures of socioeconomic status such as the SES index developed by the AHRQ (https://archive.ahrq.gov/research/findings/final-reports/medicareindicators/). The AHRQ SES

index has previously been correlated with both transplant access and outcomes (*Clin J Am Soc Nephrol* 2010; 5: 2276–2288; PMID: 20798250), based on simple linkages of the information through residential ZIP Code at registration. While it is correct that collection of census data is episodic, inadequate justification has been provided in the proposal to support the assertion that addition of data collection at the individual level for each registration is necessary to overcome the "low accuracy" of the publicly available data, and to justify the additional data collection burden.

- Transplant candidates may be reluctant to provide truthful information because of concerns that their access to the waitlist and eventual transplantation may be further limited by the perception that lower SES may correlate with non-adherence.
- Transplant centers may preferentially place organs from non-directed live donors to higher SES candidates who are perceived to be more capable of making their follow-up visits, have uninterrupted medication coverage and to be at lower risk for being lost to follow-up in the transplant program's zeal to honor the non-directed donor gift.
- Non-citizen candidates may be concerned about information sharing between government entities and lower SES may be seen as dependent on or vulnerability to becoming dependent on government aid which may, in turn, hinder their ability to become citizens.
- The proposal does not consider cost of living index
- There was concern for potentially linking SES status to post-transplant clinical outcomes, which in turn might allow in the future, socioeconomic data to increase disparity in access to organ transplantation, with programs declining low-income patients.
- There was concern that household size and household income might not accurately represent SES since households are comprised of many different combinations of people including: Married but separated, roommates, and cohabitating but not sharing finances. Depending on cultural background, it may be custom for a household to be comprised of several generations and extended family members (who may not share finances).
- There was concern that the current proposal assumes that family households share traditional mainstream financial norms, specifically related to financially supporting all members in a household (e.g., "when a candidate is too sick to work but is monetarily supported by another member of the household"). This may not be true especially for marginalized or lower SES patients.
- The proposal justification contends that the CDC and local health departments collect self-reported income and are considered reliable enough to be studied by various levels of the government. In addition to the shame many marginalized populations already experience, pre-transplant candidates are particularly vulnerable to impression management and over-compensation given the critical nature of their disease state and likely death if not approved for transplant. The uniqueness of this population puts them in a different category than samples collected from the CDC potentially making this population uniquely motivated to minimize financial distress, maximize educational and occupational experiences, and present as favorably as possible making the data collected unreliable.
- Consideration could be given to collecting occupational history since many patients are not working due to being on disability, being retired, etc. so checking "no" potentially inflates the size of the lower SES group.
- Will the "and financially supporting the patient" be assessed prior to collecting the household income? This may be confounded by the fact that many disadvantaged families share homes but do not collect enough individual incomes to help support family members even in dire situations.
- Four variables to capture that would provide some useful measure of SES, it would be educational attainment, occupation, household income, and household composition. OPTN already captures

education. OPTN captures whether someone is working for income or not, but does not capture the specific occupation (which can be derived from a standardized SES list of occupations) or the circumstances surrounding lack of employment. The decision by the MAC Committee to not expand this data element (as is currently done for Living Donors) should be reconsidered. Not knowing if the limited household income (new data element) is secondary to being retired (data element the committee decided not to expand) is problematic when measuring SES. In addition to expanding the yes-no working variable, strong consideration should be given to capturing the patient's occupation, which is an important element when assessing SES.

- It should be noted that the two new proposed data elements will not be helpful in determining access to transplant waiting lists, since the data will be captured only for those who have made it to the waiting list. Thus, it will measure access to transplantation only from wait-listing to transplant surgery – nothing else. This limitation should be acknowledged and noted. Its utility in measuring access to transplantation more broadly is negligible.
- It is unclear whether the Committee consulted with a demographer in selecting these two metrics. But if not, this should be done before moving forward. Capturing these two metrics is supported by considerable literature showing that household income is associated with healthcare access, broadly defined. Household income should be defined with more granularity and specificity to ensure that it is captured consistently across programs and providers. When being prompted for household income, for instance, patients should be told that it includes total income, earned or unearned, from all sources (e.g., wages and salaries, dividends and interest, Social Security, unemployment insurance, disability income, etc.).
- Both household income and household size are necessary to determine if someone meets the federal definition of poverty. The concept of poverty is critical to investigators and health policy experts, so adding these two variables would – for the first time – provide the transplant community with the ability to determine what proportion of transplant patients live in poverty and to assess that in the context of transplant access and outcomes.
- It should be acknowledged that these two metrics proposed to be collected, like working status, are fluid and not static; they change based on the patient's illness status, wellness, and functional capacity to work; they change based on their primary caregiver needs and the caregiver's decline in income to care for the patient; etc. So, these data tell a story – albeit an important one – at only one point in time, i.e., at wait-listing registration
- Some may believe that patients will not want to provide household income because it is too sensitive. Thus, there may be some concern that programs may be deemed noncompliant due to missing data for this element. The concern about the sensitivity of household income data is understandable, as some patients may have undeclared sources of income they do not want to reveal or they may fear losing state or federal benefits (health, nutritional, etc.) by reporting household income data to a federally contracted entity. To that end, providing patients with a range of categorical options for household income may be better than asking for a precise income amount.

Proposal Title: Addressing Medically Urgent Candidates in New Kidney Allocation Policy (Kidney Transplantation Committee)

Society Response:
The American Society of Transplantation is cautiously supportive of efforts to standardize the rare instances of "medical urgency" but offers the following comments for consideration:

- There is not support among the AST constituencies for "medically urgent" candidates to receive priority outside of the 250 NM circle.
- There is concern regarding the retrospective nature of the review of the 'Medically Urgent" status.
- The criteria for "medically urgent" status as listed in the proposal are focused on adult criteria given that many of the criteria (e.g. leg graft access) are not feasible or even possible in small children. We suggest consideration be given to development of pediatric criteria or at least modification of the proposal to indicate that the proposed criteria only applicable to adults.
- The proposal as written, does not allow for a child with failure of dialysis access (therefore meeting the definition of "medically urgent") to gain any priority over a child who is listed but stable on dialysis.

Proposal Title: Data Collection on Uterus Transplant Recipient Outcomes (VCA Transplantation Committee)

Society Response:
The American Society of Transplantation is generally supportive of this proposal and shares the following comments.

- We recognize that VCA has yet to develop accepted standards to define outcomes and to define success. This limits the ability to interpret and compare outcomes from disparate groups, particularly considering the small number of patients being treated worldwide.
- Uterus transplantation is experimental and as it becomes a more common procedure in the United States, there is a need for uniform reporting and evaluation of outcomes. The birth of a child is the desirable outcome of a uterus transplant. As such we support the collection of data on children born to uterus recipients as the outcome measure of the transplant.
- The elements suggested in Table 1 are reasonable.
- The length of stay (LOS) may not truly capture the information desired, such as LOS in NICU although it will capture a LOS that is longer than expected.
- Although it may be desirable to collect data on the subsequent development of a child, it may not be ethical, and development may have may other confounding influences. If found to be ethical, to potentially minimize the data collection burden, consideration could be given to completion of data collection forms by the child's legal guardian who would then return them to the transplant center for submission to the OPTN to address the complexities and high administrative burden of this type of data collection for the transplant program.
- The risk for congenital infection will be increased in immunocompromised mothers. Accordingly, infants should be tested for congenital CMV and/or toxoplasma if the mother is positive. Going forward, consideration should be given to collection of this data on infants born to mothers with uterine transplant.
- Admittedly the VCA Committee has enlisted the input of many stakeholders to date. Going forward it will be essential to continue to involve pediatricians, neonatologists, and ethicists.

Proposal Title: Modify Blood Type Determination and Reporting Policies (Operations & Safety)

Society Response:
The American Society of Transplantation is supportive of the proposal to Modify Blood Type Determination and Reporting Policies put forth by the OPTN Operations and Safety Committee.

The AST provides the following commentary and questions for consideration:

1. The proposal under consideration requires the OPO document "a complete history of all blood products that the deceased donor received since admission to the donor hospital in the deceased donor medical record." We believe this should also include transfusions that may have occurred at other institutions in cases where donors may have been transferred in to the eventual donor hospital. We suggest consideration of additional wording/modification of the proposal e.g.; "In the event that the donor's hospitalization involves more than one facility, the history should include blood products received at all facilities."
2. We suggest clarification of the term "source documents" that must be reviewed prior to listing candidates for transplant or determining ABO type of deceased or living related donors. For example, HLA labs often repeat and report ABO typing of donors and recipients during routine workups and will include such results on report forms along with HLA typing results. Does the statement "all source documents" then set up a requirement that all HLA reports will need to be available to the 2 healthcare professionals prior to listing? Or will this result in labs refraining from indicating recipient/donor ABO types so that it will less paperwork to review?
3. We understand that a pre-transfusion sample must be tested for A subtyping, but should consideration be given to requiring, if available, pre-transfusion samples for ABO typing as well?
4. We suggest that the Operations & Safety Committee ensure that the policy specifically address scenarios where massive transfusions have occurred. There may be enhanced safety in classifying such donors as AB for the purpose of a match run.
5. Should the definition of blood products include plasma derivatives?

Proposal Title: National Heart Review Board for Pediatrics (Thoracic Organ Transplantation Committee)

Society Response:
The American Society of Transplantation is highly supportive of the proposed National Heart Review Board for Pediatric Candidates. We agree that pediatric heart transplant decisions require experts in congenital heart diseases (CHD) and children to best determine whether exceptions are justified and to decrease geographic variation that currently exists within the system to be compliant with The Final Rule.

The Pediatric and Thoracic constituencies of AST have comments and answers to the questions posed by the OPTN Thoracic Committee:

- Having a separate NHRB for pediatric candidates ensures that pediatric physicians are reviewing pediatric cases (for which they're uniquely well suited); and that they are not reviewing adult cases (for which they may be less well suited). The only potential concern is one of workload but given that the field is generally enthusiastic about this proposal, it is not foreseen that there will be difficulties in enlisting help from transplant centers.
- The proposal is designed to increase the likelihood that exception requests are more uniformly handled in light of (1) data that shows expected wait-list mortality of the 1A exception requests is lower than that of pediatric candidates meeting conventional 1A standard criteria and (2) in some regions, 25 % of status 1A recipients were by exception, and in other regions, 0 % of status 1A recipients were by exception. Since no data was supplied in this proposal relating to the denominator of exception requests, it is unclear as to whether this regional variation was related to over scrutiny by regional review boards, vs under-requesting (or appropriate requesting) by centers within region. Pediatric centers are skewed even more than adult centers geographically.
- It is felt that as proposed, if both the primary reviewer and the alternate reviewer provide votes, only the primary reviewer's vote will count. This seems unfair given that there was a delay in the primary reviewer's completion of the work. We suggest that it may be more just to have the vote of the alternate reviewer count if they had been enlisted to do the work.
- Given that there are very significant differences in the size of pediatric heart transplant programs, perhaps consideration should be given to having larger centers have more representation.
- It seems, by the proposal as presented, that there is concern that too many exception requests may be granted by the current system of RRBs. Perhaps in the new system of pediatric NHRB consideration should be given to rather than a simple majority, that 6 of 9 votes on an initial request are necessary for approval. If a center then appeals the decision, the threshold could be a simple majority.
- We would support the idea of randomization criteria for reviewer assignment**.**
- While ideally there would be geographic balance we recommend that there should be some minimum threshold for pediatric heart cases (i.e., to be asked to participate on the board). We would agree that participants be physicians or surgeons, given the potential complexity of the medical issues involved.
- We suggest that reviewers to be limited to those from centers that have actively performed at least 2 pediatric transplants within prior 12 months.
- The appeal workgroup should be a standing work-group with a Chair and Vice-Chair so that it does not need to be recreated each time. The Vice-Chair being a voting member of the Workgroup and the Chair voting only in cases of tie or similar.

- Three days is felt to be the correct time to review and vote but consideration should be given to a mobile app-based notification and entry
- Appeal to the entire Thoracic Committee is unnecessary. Three layers of appeal is adequate.
- Agree with the 72-hour time limit for voting.
- If a member of the Committee-level appeal workgroup has already reviewed the application as a reviewer on the NHRB, that reviewer should be allowed to participate in the review of the appeal.
- If reviewers serve limited terms, if two reviewers from one program are removed for inadequate performance, future members to the review board from the same program would be allowed.
- Cardiomyopathies are the area where there is the greatest need for guidance.

Proposal Title: NLRB Operational Guidelines Update (Liver and Intestinal Organ Transplantation Committee)

Society Response:
The American Society of Transplantation is supportive of this proposal, and offers the following suggestions that have the potential to further improve NLRB efficiencies

1. Given the recent implementation of the new MMaT MELD upgrade and the acuity circle allocation system, the MELD scores at which HCC patients are being transplanted should be closely monitored to determine how the new acuity circle allocation system is impacting HCC patients. Consideration should be given to updating MMaT every 3 months instead of every 6 months to better stay abreast of the real-time impact that the new system may have on the MELD exception candidates.
2. Consideration that previously treated HCC lesions which were within Milan criteria at the time of the presentation should be granted automatic acceptance for the MELD upgrade.
3. Consideration of standardization of data presented to the NLRB to capture essential elements and minimize submissions with long and confusing narratives which may potentially lead to an unfavorable decision.
4. Monitoring of reviewer adherence to the NLRB guidance. Some AST members have noted that some cases have been declined by reviewers even when patients fit the exception criteria provided in the guidance document. For example, reviewers who have high appeal rates can be flagged for a more in-depth examination of reviews by UNOS Liver and Intestinal Committee to determine if there is a consistent trend of unjustified denials and a re-direction towards the guidance document can be implemented.
5. Consideration for a 6-month rather than 12-month period for removal of inactive reviewers.

Proposal Title: Update to VCA Transplant Outcomes Data Collection (VCA Transplantation Committee)

Society Response:
The American Society of Transplantation is supportive of this proposal. VCA transplantation is rapidly evolving. There is a need for the OPTN to be responsive to rapid changes in the field and to ensure that data being captured are meaningful to patients, providers, and policy experts. The removal and addition of data elements to the head and neck, upper limb, and uterus transplant TRR and TRF forms has been thoughtfully considered by the Committee, with critical input from key stakeholder groups.

The VCA Committee has identified three QOL assessment tools and asks for comments about which one should be selected for inclusion on the TRF. The three are the SF36, SF12, and PGI.

- The PGI, which is a novel patient-centered tool, should be removed from consideration. It requires open-ended responses from the patient, which makes data mining, conversion, validation, and interpretation much more challenging and less likely to be used by researchers or policy experts going forward. Additionally, use of the PGI – considering its format – would place a much larger administrative burden on transplant programs to administer the questionnaire and enter the data onto the TRF.
- The SF36 and SF12 are widely used, have been extensively validated in multiple languages, and provide standardized scores reflecting multiple domains of health-related QOL. The SF12 obviously provides less granularity than the SF36, but is less burdensome for patients and programs. If the Committee's intention to use one of these three measures, We would support use of the SF12. Both, however, will place additional administrative burden on transplant programs.

Overall, while the AST agrees with the desire to collect this QOL information in the context of VCA transplantation, we are concerned that compliance will be low – both with patients who do not complete the measure due to time constraints or lack of follow-up and for programs who will have to develop a process for collecting, tracking, and entering the data. Even when done as part of highly resourced, NIH-funded transplant outcome studies, rates of QOL assessment completion are generally less than 70% the further removed from transplant surgery the assessment gets. For this reason, we strongly support additional discussion and consideration of alternative strategies to capture and share health-related QOL through program consortia rather than through a required OPTN data element that may be used as a measure of program performance and place high administrative burden on programs.

While the AST constituencies concurred with the proposal in Table 2 without modifications and additionally supported the modifications noted in Tables 3, 4, 7 and 8, there was not support for the removal of the "Skin changes noted with acute rejection" in Tables 5 and 6. Currently, the monitoring for rejection is the skin, thus, data on skin changes should be collected during rejection. Data elements collected for biopsy data are dissimilar to those observed with skin changes. Thus, failure to collect visual changes will impair the ability to comprehensively monitor the graft leading to poorer outcomes.

Proposal Title: HLA Equivalency Tables Update (2020)

Society Response:

The American Society of transplantation supports this proposal as written without further comment.

Proposal Title: Distribution of KI and PA from Alaska (Kidney and Pancreas Transplantation Committee)

Society Response:

The American Society of Transplantation supports this proposal without further comment.

Proposal Title: Guidance on Blood Type Determination

Society Response:
The American Society of Transplantation is supportive of this excellent guidance document. We believe it should provide significant assistance to OPOs, Transplant Centers, and Laboratories in addressing the complexities of ABO determination, especially in cases where results are indeterminant or discrepant. This type of document is invaluable and as such we would ask that consideration be given by the OPTN Committees to the creation of comparable documents to assist in similar scenarios such as indeterminant testing for infectious diseases

We have a few comments, some minor, for your consideration and one question:

1. Under Conventional Methods for ABO Determination, we are confused as to why Rh (D) typing is included in the forward group assessment, since Rh typing is not required or performed for organ transplant purposes. Alternatively, many labs also utilize Anti AB commercial reagent to confirm the results of Anti A or Anti B commercial typing reagents, and this is not mentioned. If the decision is made to still include Rh, please consider stating that Rh typing is not required. A minor point is the addition that the endpoint assessment for the tube method is agglutination graded 0 – 4 +.
2. On page 7 under Transfusion, patients who receive emergency blood group O transfusions when the blood type of the patient is not known may also have significant amounts of Anti A or B transfused, which could lead to discordant results. Also, if a large amount of AB plasma is transfused, this could also lead to discordant results, since the expected Anti A or B antibodies for a group O patient may be weak or absent. The word native is confusing here.
3. Under Alternative Testing Methods for Determination of Blood Type: DNA based… a note should be added regarding donors that might have received stem cell transplants previously, suggesting that buccal swabs also be used as a source of DNA when using DNA based methods for ABO determination.
4. Throughout the document different terms are used to describe ABO discrepancies: (discordant, incongruent, inconsistent, conflicting). We suggest using discrepancy, which is the term most often used in the blood bank field.
5. When DNA testing is needed does the Committee have any estimate of how this will impact timing of transplant and CIT?