ASTS
American Society of Transplant Surgeons

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Kenneth A. Andreoni, MD
President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear Dr. Andreoni:

The American Society of Transplant Surgeons (ASTS) has reviewed and considered the following seventeen proposals out for public comment through June 13, 2014. Below is the Society's position on each proposal.

Proposal #1: Kidney Paired Donation (KPD) Histocompatibility Testing Policies (Kidney Transplantation Committee)

ASTS **supports** this proposal regarding requirements for histocompatibility testing on donors and recipients in the OPTN KPD program. ASTS is pleased that the committee considered recommendations from the March 29-30, 2012 KPD consensus conference in Herndon, VA in formulating this policy proposal.

Proposal #2: Proposal to Cap the HCC Exception Score at 34 (Liver and Intestinal Organ Transplantation Committee)

ASTS **supports** this proposal to cap the HCC exception score at 34. Share 35 was not intended for stable HCC patients where time on the waiting list would overwhelm severity of illness thereby usurping the spirit of the allocation scheme.

Proposal #3: Proposal to Delay HCC Exception Score Assignment (Liver and Intestinal Organ Transplantation Committee)

ASTS **does not support** this proposal . This short term approach does not address the underlying problems associated with geographic disparities.

<u>Proposal #4</u>: Proposed Membership and Personnel Requirements for Intestine Transplant Programs (Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees)

ASTS **supports** this straightforward proposal aimed at establishing criteria for Program, Surgical Director, and Medical Director of Intestinal Transplant Programs.

Overall, this is an important proposal to move the field of intestinal transplantation onto equal playing field as other solid organ transplants. Further, it is a means to ensure patient safety as these transplants should be performed only at programs seeking and obtaining approval. ASTS observes that the bar is quite low for obtaining credentialing; so low that the need for TWO alternate pathways to obtain approval seems un-necessary. ASTS encourages the committee to consider the following as it finalizes its proposal.

1. Wording regarding the ASTS accredited training program needs to be clarified. Given current ASTS training paradigms, ASTS suggests that the surgeon need to have completed an ASTS fellowship in liver and intestine transplantation.
2. Why does the Primary Physician need to observe two operations? Is this a requirement for the Primary Physician in other organs such as liver or kidney. If this is in keeping with other standards, then it can stand. If not, this Primary Physician should not be held to a different standard than a Primary Hepatologist or Nephrologist.
3. The combined program provision is difficult. There are not many adult gastroenterologists interested and active in this field. As such many programs use pediatric GI specialists to assist in the care of these patients. Therefore, mandating that an adult GI be "involved in the care" when they lack the expertise in the area seems senseless. While the opposite may also hold true, this situation rarely exists given the paucity of adult GI physicians in this specialty area. ASTS suggests that there is one designated ADULT or PEDIATRIC GI Primary Physician responsible for the care of intestine transplant recipients.

<u>Proposal #5</u>: Proposal to Require the Collection of Serum Lipase for Pancreas Donors (Pancreas Transplantation Committee)

ASTS **supports** this proposal which would require the collection of serum lipase for pancreas donors.

<u>Proposal #6</u>: Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation (Ad Hoc Disease Transmission Advisory Committee)

ASTS remains concerned with the PHS "*Guideline for Reducing Transmission of HIV, HBV and HCV Through Organ Transplantation*" ("Guideline") and **does not support** the adoption of a policy requirement for *<u>all donors</u>* to be tested for both anti-HCV and for HCV RNA by NAT. The ASTS remains committed to the optimization of acceptable numbers of organs for transplantation in the US. Our concern is that this policy will tangibly reduce the numbers of available, acceptable organs for people in the US, with little to no impact upon the numbers of transmitted infections.

The document makes strong recommendations based on weak evidence and recommends the performance of NAT testing (for HCV) for all potential donors, without recognizing the potential impact of universal NAT testing on organ supply. The recommendation fails to address the impact ofdiscordant or false positive results and the effect of the testing requirements upon the logistics of organ procurement and allocation. Currently, a significant percentage (~ 20%) of organ offers are made without available pathogen testing, increasing risk to significant numbers of potential organ recipeints. Anecdotal discussion with OPO leaders recognizes that transportation and logistics associated with NAT adds more complexity and time to the organ donation evaluation process. From 2008-2013, from the 48,492 deceased donors, there have been 0 HIV, 5 HBV and 6 HCV proven/probable transmissions identified by DTAC from deceased organ donors (only 1 HBV and 1 HCV were from "high risk" donors). A few of these may have been prevented had universal NAT been available, but some transmissions were from human error or failure of commercially available NAT to detect viral nucleic acid and not solved by NAT. However what is not available is the number of donors that did not materialize due to indeterminate results or logistics. Disease transmissions can **never** be eliminated, and it is incumbent that the OPTN balance the efficiency of the mandatory safety and quality organ donor assessement tools with its effect and impact upon organ availability. With 12,089 people removed from the national waitlist in 2013 because they died or became too sick, we do not see the logic of mandating a testing strategy that the joint societies' experts concluded would decrease and constrain organ availability to a much greater extent than preventing disease transmission: a conclusion that is supported by the existing data. The society asserts that the magnitude of the problem does not require a "fix" that will likely exacerabate the organ shortage. Without further study or demonstable need, the proposed processes should not be mandated.The expanded definitions used by the PHS to identify "increased risk" donors are so broad as to become almost irrelevant. Before 2010, high risk donors comprised 7-9% of the deceased donor population. In the first part of 2014, with most OPOs using the new "increased risk" donor identification, 17% of deceased donors are identified as increased risk. If almost 1/5 donors are recognized as "increased risk", what is the relevance? The "increased risk" language puts undue fear and concern into the potential recipient population; falsely, in contrast to the risk of death on the waitlist. In the event that universal NAT is mandated, a more rational approach to donor identification would be to remove the "increased risk" moniker and assume that of the "universal" donor precaution, consistent with the "universal precaution" stance adopted in hospitals. As the currently available NAT triplex platform provides assessment for HIV, HCV and HBV, we should consider a simpler system that removes donor stratification by behavior and its' attendant worry.

We, as a transplant community, worry about disease transmission each and every day, and we are deeply committed to better defining the risks and reducing the possibility of unintended transmission of all donor-derived disease to our patients. However, we cannot approach this issue using a single-lens. Practicing clinicians also must worry about transmission of other diseases, organ availability, death on the waiting list, clinical outcomes, risk/benefit, and most importantly, how to accurately and reasonably inform our patients about these risks. We do not feel that the current proposal is appropriate for the needs of the community or the patients waiting or having received an organ transplant.

Finally, we notice that the committee at times calls for guidance documents as opposed to new policy. Since many OPTN guidance documents have the potential to influence patient care, we believe they should be evaluated with the same deliberative review as potential policy. At a minimum, all potential guidance documents should be subject to review by the professional societies so that the voices of the community can be heard and considered prior to being presented to the OPTN board of directors for approval. Furthermore, there may be topics for which a public comment period is also appropriate.

Proposal # 7: Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types (Histocompatibility Committee)

The proposal includes the following changes:

1. *Makes consistent the list of HLA loci required to be reported for deceased donors across organ type both when policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for heart, heart-lung, or lung allocation). The proposal newly requires HLA typing for deceased liver donors if requested by the candidate's transplant program.*

ASTS **supports** this change. With recent evidence for the role of antibody mediated rejection in long term liver graft outcomes, this information may be importance. As it stands, 92% of deceased donors in the United States are kidney or pancreas donors and thus are already required to have HLA typing. This proposal would provide consistency among the donor pool.

2. *Requires molecular typing to be performed on all deceased donors, both when policy requires HLA typing be performed and reported on the deceased donor prior to allocation (i.e. for kidney, kidney-pancreas, and pancreas allocation) and in instances where HLA typing is required only if requested by the candidate's transplant program (i.e. for deceased heart, heart-lung, lung, or liver donors).*

ASTS **supports** this change as the majority of labs are using molecular typing.

3. *Adds HLA-DQA and HLA-DPB to the list of HLA loci required to be reported for deceased donors. As proposed, these fields will only be programmed into DonorNet® for physicians to use in making donor acceptance decisions.*

ASTS **supports** this proposal. There is evidence that antibodies against these antigens do cause positive crossmatches and antibody mediated rejection, across most types of allografts. The vast majority of labs performing HLA typing have the technological capability to identify these antigens, so it would be a matter of implementation to achieve this level of typing. There may be some added costs associated with these tests, but this would be offset by decrease in the likelihood of having positive final crossmatches, longer ischemic times, and potential organ discards.

With regards to the question of whether it is sufficient to have this donor HLA information recorded in DonorNet to use when making donor acceptance decisions, ASTS would favor adding unacceptable antigen fields for these loci and program the system to automatically avoid those donors when unacceptable antigens are listed. Again this would be most consistent with what is done for the HLA information gathered. It is up to the individual program then to decide how they want to fill in those fields, rather than trying to make that decision in the middle of the night when the organ is initially offered.

4. *Aligns requirements for deceased pancreas islet donors and candidates with those of pancreas donors and candidates.*

ASTS **supports** this proposal.

Proposal #8: Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Living Donor Committee)

ASTS **supports** this proposal as written and based on recommendations from the Joint Society Workgroups.

Proposal #9: Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors (Living Donor Committee)

ASTS **supports** this proposal as written. ASTS notes that the newly designated 14.6.C addresses the allocation of non-directed kidney donors but fails to address the allocation of non-directed liver donors.

Proposal #10: Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures (Living Donor Commitee)

ASTS **supports** the intent of this policy to require reporting of aborted cases in an effort to monitor for activity that may indicate safety issues and to better quantify how often aborted cases occur. However, the current policy proposal uses the verbiage "after donor has received anesthesia" which we perceive as too vague. For example, if a donor has a vaso-vagal response in preop after receiving some sedation prior to entering the operating room and the case is canceled, would that need to be reported? ASTS would suggest a more definitive time point, ie "after first skin incision is made" as the point when the donation procedure actually begins.

It is also unclear from the policy whether the mandatory follow-up monitoring of a living donor would apply to a donor where the case was aborted. This needs to be clarified. ASTS suggests language such as "If the organ that was planned for removal was surgically manipulated but not removed, mandatory follow-up should apply."

Proposal #11: Proposal to Clarify Data Submission and Documentation Requirements (Membership and Professional Standards Committee)

ASTS **supports** this proposal designed to ensure accurate data reporting. The proposal supports the intent for accuracy and action if deemed necessary upon review. A key component of this proposal will be educational resources for the transplant center to clarify what is an acceptable source document to verify accuracy and how to monitor and ensure accuracy of the data submitted.

Proposal #12: Proposal to Allow a MPSC Recommendation to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area (Membership and Professional Standards Committee)

ASTS **does not support** this proposal as written. The qualifying criteria for key personnel have been developed over many years and are designed to provide the foundation for minimum program standards. Allowing a program to bypass these criteria based on geographic location is counterproductive to the creation and enforcement of unified OPTN polies.

Proposal #13: Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Operations and Safety Committee)

ASTS **supports** this proposal desgined to improve safety and consistency.

Proposal #14: Proposed ABO Subtyping Consistency Policy Modifications (Operations and Safety Committee)

ASTS **supports** this proposal desgined to improve safety and consistency.

Proposal #15: Proposal to Allow Non-substantive Changes to the OPTN Policies and Bylaws (Policy Oversight Committee)

Overall, ASTS **supports** the goal of this proposal to allow the OPTN contractor to correct clerical errors. The allowable changes are narrow and must be reviewed by the executive committee retrospectively. However, ASTS is concerned that "grammatical error" changes would be allowed. It is possible to make a minor change in grammar that results in substantial change in content. While the safety net is the requirement to have the executive committee review retrospectively, these changes could create confusion in the interim.

Proposal #16: Proposal to Notify Patients Having an Extended Inactive Status (Transplant Coordinators Committee)

ASTS **does not support** this proposal. ASTS does support aggressive waitlist management which is important for both patients and the transplant centers. However, there are numerous ways to communicate with the patient that may remain on hold, including discussions in-person, by telephone, by email or in writing. ASTS opposes initiating an unfunded mandate to notify patients at 90 days, 365 days and yearly thereafter.

<u>Proposal #17</u>: Proposal for Adolescent Classification Exception for Pediatric Lung Candidates (Thoracic Organ Transplantation Committee)

ASTS supports this policy which would replace the temporary policy permitting lung candidates less than 12 years old to request an exception from the Lung Review Board (LRB) to be classified as an adolescent candidate for the purposes of prioritization by the lung allocation score (LAS).

Thank you for the opportunity to comment on these proposals. Please do not hesitate to contact me or Kim Gifford, ASTS Executive Director, if you have any questions or require additional information.

Best regards,

Alan N. Langnas, D.O.
President