



Improving Human Life by Advancing
the Field of Transplantation

AST BOARD OF DIRECTORS 2013-2014

PRESIDENT
Daniel R. Salomon, MD
The Scripps Research Institute

PRESIDENT-ELECT
Kenneth A. Newell, MD, PhD
Emory University

IMMEDIATE PAST-PRESIDENT
Roslyn B. Mannon, MD
University of Alabama at Birmingham

TREASURER
Kimberly Ann Brown, MD
Henry Ford Hospital

SECRETARY
Anil Chandraker, MD, FRCP
Brigham and Women's Hospital

COUNCILORS-AT-LARGE
James S. Allan, MD, MBA
Massachusetts General Hospital

Rita R. Alloway, PharmD
University of Cincinnati

Ronald G. Gill, PhD
University of Colorado, Denver

Michael G. Ison, MD, MS
Northwestern University

Paul Martin, MD
University of Miami

Dianne B. McKay, MD
University of California, San Diego

Larry B. Melton, MD, PhD
Baylor Medical Center, Dallas

David P. Nelson, MD
Integrus Baptist Medical Center of Oklahoma

Thomas Pearson, MD, DPhil
Emory University

EXECUTIVE VICE PRESIDENT
Susan J. Nelson, CAE

EXECUTIVE DIRECTOR
Libby McDannell, CAE

MEMORANDUM

To: Dr. Kenneth Andreoni, UNOS President
Mr. Brian Shepard, UNOS CEO

From: Ms. Libby McDannell, Executive Director
American Society of Transplantation (AST)

RE: AST Comments on OPTN/UNOS Policy Proposals

Date: June 13, 2014

On behalf of the American Society of Transplantation Board of Directors, I am attaching the Society's comments on the seventeen OPTN policy proposals currently out for public comment.

The AST has reviewed and provided comments on every proposal. We are supportive of proposals 1-10, 12, 14, 15, and 17 with consideration of the enclosed comments. We are not supportive of proposals 11, 13, and 16 as currently drafted and our comments provide the rationale.

Please let me know if there are any questions about our comments. Thank you for the opportunity to provide feedback on these policy proposals.

Cc: AST Board of Directors
Dr. Maryl Johnson, AST's UNOS Board Representative

NATIONAL OFFICE
15000 Commerce Parkway, Suite C • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.439.9982 • info@myAST.org • www.myAST.org

GOVERNMENT RELATIONS
William Applegate, Director of Government Relations • Bryan Cave, LLP
1155 F Street, NW • Washington, DC 20004
202.258.4989 • bill.applegate@bryancave.com

**WORLD TRANSPLANT
CONGRESS 2014**

July 26-31, 2014
San Francisco, CA

Proposal #1: [Kidney Paired Donation \(KPD\) Histocompatibility Testing Policies](#)

Comments: We find the proposal strong and well written. The AST supports the proposal. We believe the changes will increase efficiency in arranging compatible matches and facilitate transplants for candidates enrolled in KPD.

Proposal #2: [Proposal to CAP the HCC Exception Score at 34](#)

Comments: Patients on the liver transplant waiting list with a MELD exception for HCC have a significantly lower risk of drop-out compared to non-HCC patients. In some regions the 3- monthly increase in the HCC MELD exception may be disadvantaging sicker patients, especially at the high end of MELD scores where the 'Share 35' policy dictates that there be regional sharing when the MELD (biological or HCC exception) is > 34.

The wording and intent of this policy proposal are clear, and will have the effect of preventing the unintended effect of the 'Share 35' policy where patients with HCC MELD exceptions > 34 (who are not likely to drop from the waitlist) may receive organs ahead of sicker non-HCC candidates.

This policy further highlights the difficulties of using MELD exceptions and trying to match the potential for waitlist dropout between those stratified with MELD scores and those with MELD exceptions. This problem is especially poignant where the HCC exception is concerned. Though initially resource-intensive, another route would be to move to an allocation system that takes both waitlist dropout and post-transplant survival into account. Such a model would allow for abolishment of the MELD exception, which is proving so difficult in HCC (as well as other conditions where the MELD does not predict outcomes).

In the absence of creating another allocation system and in light of the 'Share 35' policy, the AST supports the current proposal.

Proposal #3: [Proposal to Delay HCC Exception Score Assignment](#)

Comments: This proposal addresses one of the most difficult problems facing the liver transplant community at this time: how to equalize access to liver transplant and improve post-transplant outcomes in regards to patients getting a MELD exception for HCC compared to patients without HCC. It has become clear that patients with MELD exceptions for HCC have a lower risk of drop-out than patients without HCC (thus HCC patients have increased access to liver transplant). At the same time, post-transplant outcomes may be worse for patients transplanted rapidly after getting the HCC MELD exception (compared to those who wait longer on the transplant list). This latter point may be due to the fact that some patients with HCC, though within transplantable criteria, have occult metastatic disease that only becomes apparent by observing the patient for some time.

The effect of this proposal would be to delay granting a MELD exception for HCC for 6 months. The

intention of this proposal would be to equalize drop-out rates between HCC and non-HCC patients, as well as avoid transplanting patients with occult metastatic disease at the time they are placed on the transplant list.

Unfortunately, this policy change will only make a very small difference in the “HCC MELD exception” problem. It will prevent centers with low wait times from transplanting “biologically aggressive” tumors that may result in poorer post-transplant outcomes. It will have no effect on centers where the wait times are ≥ 6 months. While this is a small step in the right direction, it in no way addresses the larger issues surrounding liver transplantation for HCC given the current MELD exception allocation scheme.

Increasing data shows that compared to patients with standard MELD allocation, patients with HCC exceptions have lower waitlist dropout yet do worse post-transplant (decreased survival comparatively). In addition, the current HCC exception policy is largely responsible for the increase in MELD score at transplant across the country, which exacerbates the situation for non-HCC candidates.

Though initially resource-intensive, another route would be to move to an allocation system that takes both waitlist dropout and post-transplant survival into account. Such a model would allow for abolishment of the MELD exception, which is proving so difficult in HCC (as well as other conditions where the MELD does not predict outcomes).

Barring such a radical change in our allocation system, the proposal as written is reasonable and the AST supports it.

Proposal #4: [Proposed Membership & Personnel Requirements for Intestine Transplant Programs](#)

Comments:

AST 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. AST 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. AST encourages the committee to consider the following as it finalizes its proposal.

1. 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.
2. 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.

Proposal #5: [Proposal to Require the Collection of Serum Lipase for Pancreas Donors](#)

Comments: Overall this is a well-written proposal. Serum lipase levels are crucial to the assessment of the pancreas donor. These levels must be interpreted in the context of baseline laboratory ranges, and therefore, the requirement to report the upper limit of normal is necessary. The AST is in complete support of this proposal.

Proposal #6: [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](#)

Thank you for the opportunity to comment on the UNOS policy. We will address the specific questions in the policy document below:

1. We defer to OPO personnel to comment on this.
2. The issue here is the risk of discarding organs unnecessarily due to false-positive HCV NAT vs. accepting such organs without completion of additional testing that ultimately confirms a true HCV-infected donor. With the development of simpler, safer and nearly 100% effective anti-HCV regimens becoming increasingly available the latter scenario might be considered acceptable provided clinicians and recipients are aware. To counterbalance any possible false positive test results, it is possible that NAT will identify patients with who have cleared or have been effectively treated (i.e. serology positive, NAT negative) for HCV. Given emerging HCV treatments, the pool of seropositive, NAT negative donors will likely increase significantly.
3. The recipient should be made aware during the informed consent process that such a situation could occur.
4. The potential legal and ethical issues can be addressed with full disclosure and appropriately obtained consent. The informed consent process should incorporate the fact that results for HCV NAT can be obtained after transplant. If there are no risk factors present in the donor, a false positive HCV NAT is a possibility.
5. We believe that this scenario would be uncommon. However, in this case it would likely take several additional hours to repeat the test and/or do individual NAT tests to resolve the issue.
6. We believe that the lab is obligated to report all tests performed even if not ordered. This is clearly another pitfall of recommending universal NAT for HCV (but not for HIV).
7. Firm data are not available in donors; however, we strongly suggest that once the policy is implemented, these data be prospectively collected. One study (Kakaiya et al., Transfusion 2011) reported that in over 1 million blood donations, there were 51 positive HCV NAT and 7 positive HIV NAT. Of these positive NAT, 77% were deemed false positive.

8. This approach may increase the risk for unexpected transmissions. We agree that various subpopulations have lower risks than others. However, the PHS guidelines have advised universal HCV NAT and excluding subpopulations would once again lead to a risk-based approach. Before excluding subgroups, it would be important to see data on the reliability of history under these circumstances and whether the risk is actually lower.
9. We believe that the wait list screening criteria for serology and NAT results for these two viruses can be similar.
10. We agree that the short-term dialysis/CVVH does not carry the same risk for HCV. We would suggest that a clarification be made.

Additional comments:

For PHS guideline #8, we note that there is a split vote. Despite this, the use of universal HCV NAT is recommended. Many feel that HCV NAT should be done for all increased risk donors, but not for standard risk donors; a minority agreed with the policy as written. If universal NAT is to be implemented, we recommend prospective data gathering as to the rates of false positives and seropositive/NAT negative results.

With regards to decisions of informed consent, a standardized inform consent may better inform risk when transplanting organs from increased risk donors. We support the development of a standardized consent which is reviewed with the patient at the time of listing as well as when the patient is called in for a transplant.

Although the AST supports policies to minimize the possibility of disease transmission through transplantation, it needs to be kept in mind that the risk vs. benefit of accepting a particular donor for a particular recipient has to be individualized. For some candidates, accepting a donor with the potential (although low likelihood) for disease transmission may be preferable to the near certainty of the death of a recipient. Transplantation will never be a zero risk proposition and informed consent of the recipient about the potential of disease transmission is the important thing rather than trying to completely eliminate the possibility of disease transmission.

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

Comments: Overall this is a well-written proposal and a reasonable update to the histocompatibility requirements, but does this proposal fail to go far enough?

1. The proposal outlines HLA-typing of the candidate that is required to be reported. The proposal differs from that recommended by the KPD consensus conference. The KPD consensus conference recommends adding HLA C and DR51/52/53. These recommendations were made secondary to the large number of highly sensitized patients in the KPD pool and were based on recommendations from ASHI. We would favor having a similar requirement for the highly sensitized candidates (PRA>80%) on the deceased donor list.
2. While it is clear that the histocompatibility affects different organs differently, it seems like requiring different reporting timelines may confuse matters. Why not: 1) require the (new) suggested HLA (molecular) typing for every organ donor; 2) report automatically in UNet in appropriate fields prior to organ offers. It seems that there is the potential for confusion with a

policy that requires different reporting times for different organs, especially when it may not be clear at the offset what organs may be donated from a particular donor.

We were asked to comment as to whether our transplant centers screen candidates for antibodies to HLA-DQA and HLA-DPB and if so, is it sufficient to have this donor HLA information recorded in DonorNet to use when making acceptance decisions or do unacceptable Ag fields for these loci need to be added?

Our centers do in fact screen for both DQA and DPB. We routinely are unable to rely on virtual XM results because of recipient DP antibody, which requires us to run a preliminary crossmatch. For local donors this is less problematic as we have ready access to donor nodes. However, this often limits our ability to accept imports secondary to concerns about cold ischemia time or an unwillingness on the part of the offering OPO to grant us local back-up. Adding donor HLA information for these loci to DonorNet would be very useful. We have concerns about adding unacceptable Ag fields for these loci, in particular DQA. Occasionally, the donor has a DQA-DQB specificity that may have a lower MFI than the mean DQA which is called unacceptable. The DQA-DQB specificity MFI could be acceptable in some transplant programs. If the DQA was listed unacceptable this patient would not come up on the list.

We would request that UNOS work closely with ASHI to ensure requirements are consistent.

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

Comments: The AST supports this proposal and wants to thank all who contributed to its development. We do offer the following comments:

1. Regarding Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors. The surgical risks specific to kidney donation are vague in comparison to the liver donation specific risks. We would like to see the same language used in both cases. Specifically, the bullet under liver donation specific risks that reads: "hernia, wound infection, scars, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure" should be included in the kidney donation specific risks as well.
2. There was significant discussion regarding Table 14-3, point B, which contains the following language: "Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile." Some proposed that the language should be updated based on more recent publications that suggest the risk of ESRD in living kidney donors may be increased somewhat compared to the general population (i.e., JAMA.2014;311:579-586), however others felt that this data was still controversial and not supported by other studies and that policy, which does not change rapidly, should likely not specify the specifics of the risk. In the final analysis, it is recommended that since the risk of ESRD in the living donor is continuously being reassessed as new data are defined, each living donor program should be required to include specific information concerning the risk of ESRD in the living donor in the consent process with citation of the source of the information they provide.
3. Tables 14-2 and 14-5 state that the recovery hospital is required to provide the living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from

the most recent SRTR hospital-specific reports. In doing this, care must be taken not to inform the donor about where the kidney will be transplanted, to protect the identity of both non-directed donors and recipients.

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

Comments: The AST supports this proposal. We believe it offers consistency for work-up of all living organs donors and clarifies guidelines for the evaluation of living kidney and living liver donors.

We do offer two minor comments:

1. Table 14-6, Requirement for Living Donor Medical Evaluations, Endemic transmissible diseases. “Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.”
 - a. We recommend provision be made for sharing center-specific protocols in addition to testing results in the context of paired exchange, in which the receiving center may lack expertise in endemic disease risk at the donor testing/recovery center.
2. 14.4 E, Table 14-9 – Exclusion criteria for all living donors, “Active malignancy, or incompletely treated malignancy.”
 - a. We believe added clarification would be helpful. Not all tumors are considered to have the same risk of transmission or recurrence; in addition, patients who have finished their treatment may still have higher risk of recurrence or cancer transmission. We recommend that the policy reference as well – written piece such as recommendations from the Consensus Statement of the Amsterdam Forum, or better encompass these considerations in the state exclusion criteria. For example, it could state: “active malignancy or incompletely treated malignancy with risk of transmission or recurrence, or treated malignancy considered at higher risk of recurrence or cancer transmission.”

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

Comments: The AST supports the proposal for mandatory reporting of aborted living donor organ recovery procedures post anesthesia administration to UNet through the Patient Safety Portal. The proposal should improve transparency and will not represent an added burden or a need for significant additional resources in transplant programs to maintain compliance. We also do not believe that gathering this information will negatively persuade living donors to move forward. On the contrary, it will provide a greater degree of transparency.

Proposal #11: [Proposal to Clarify Data Submission and Documentation Requirements](#)

Comments: The AST agrees that the data submitted on the data collection forms should be accurate. While the vast majority of information should already be contained within medical records and documented according to standard medical practice, the process of collecting the data from multiple sources and different systems / specialties and having it ready for a potential audit in the future will represent a challenge and burden to transplant programs.

We have two specific questions:

1. Some of the information included on the various forms does not reflect discrete data elements, but interpretation from discussions with the patient or review of records. These items include such things as physical capacity, work status, academic progress, angina, peptic ulcer disease, symptomatic cerebrovascular disease, symptomatic peripheral vascular disease, etc. Will the data accuracy and document verification apply only to discrete elements of data on the forms where there is no room for interpretation or also to items as listed here where there is some judgment/discretion involved? If the latter, how will the “accuracy” be determined?
2. What documentation will programs be required to provide to verify the accuracy of the data submitted? Does it need to be in the transplant hospital’s medical records or files or can it be data that are abstracted from outside medical records and entered that the transplant hospital could access if requested to do so? If the latter, what time would a program be allowed to have to provide primary source documentation? The policy needs to be clearer about what primary source documentation the transplant center needs to have and for which data elements on the forms in the case of an audit.

The AST is not supportive of this proposal without further clarification.

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](#)

Comments: In general the AST supports this proposal. In response to the specific request for comment, this does not appear to be a suitable setting to debate the appropriateness of current board approved qualification criteria, the details of which would need careful consideration prior to recommending removal of these criteria when considering approval for all transplant programs regardless of location. The current policy should be maintained for new program applications not considered “geographically isolated” as defined by proposal 12. Regarding patient safety, OPTN and the community as a whole will need to assume a higher potential risk to patient safety if a program is allowed to function without meeting all approval criteria and this risk must be balanced by the benefit of offering transplant services to individuals in isolated areas who may otherwise have no access to these treatments. In this regard, keeping patients fully informed should be a top priority. The following should be required of transplant programs operating as a result of this bylaw: 1) disclosure to ALL PATIENTS the nature of program approval via special consideration, including the specific reason(s) why board-approved criteria were not met, and the potential risk that may result, and 2) provision to all patients the location and contact information for the nearest transplant center offering the required services and meeting full board

approved criteria. In addition the OPTN should consider a more rigorous protocol for monitoring outcomes than would otherwise be implemented for transplant programs meeting all board-approved acceptance criteria. It is not yet clear that the CUSUM / Bayesian reporting methodology would provide for early detection of "problematic" outcomes.

Proposal #13: [Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications](#)

Comments:

ABO Blood Type Reporting: Although the proposed changes in ABO verifications for donors and recipients are intended to lead to improved safety, they will initially represent a burden to both OPOs and transplant centers to implement and document. Although the requirements are quite clearly spelled out in Table 5-1 and Table 5.6.B, careful and ongoing education will be required to increase the likelihood of OPO and transplant center compliance with the proposed verification changes. Guidance as to best practices as to how to successfully perform the required verification with the least additional burden would be helpful.

The AST agrees with the proposed policy that will require both deceased donor ABO typings to be completed and reported “prior to the match run” versus the current “prior to incision”. The proposed change will reduce the possibility of matches being performed on one potentially erroneous ABO blood typing result. Having two separate ABO tests with two-person verification and reporting for deceased donors prior to the match run will align, in principle, with the current requirement for waitlisted candidates. All living donor candidates will also fall under this safety check should the mandate be enforced for wait list registration of living donor cases prior to transplantation.

Currently in UNet, only one person is required to list a candidate as willing to accept an ABO incompatible organ. The AST disagrees with the proposal which recommends a programming change in UNet that will ONLY warn users to verify that an ABO incompatible transplant is clinically appropriate for each registration before the candidate is permitted to receive such offers. We recommend a proposal rewrite to mandate the two step/2 reviewer(s) process.

ABO Compatibility Verifications: The AST agrees with the proposed organ recovery verification changes for both deceased and living donors. For deceased donors, host OPOs will be responsible for conducting verification prior to organ release to the transplant hospitals. This represents a change from only requiring a time-out and blood type verification when deceased donor organs will remain within the same operating room suite. The timing of the recovery verification has been moved up from “prior to leaving the operating room” to “prior to induction of anesthesia for living donors”. This verification will apply to all living donor organ recoveries not just to those that remain within the same facility as is currently in policy.

The supporting evidence is that a verification done after living donor organ removal, but prior to leaving the operating room is not the safest time.

We also agree with the two other conditional items being proposed: a check-in at organ arrival if the organ will be arriving from a different operating room suite and a pre-procedure verification done prior to induction of anesthesia if transplant surgery will begin prior to organ arrival. The check in can be combined with the final verification if the organ is delivered immediately into the operating room with

no break in chain of custody. If surgery is planned to begin prior to organ arrival, the proposed pre-anesthesia verification will add to patient safety. If an accidental incompatibility is discovered after surgery has started when the organ arrives, then patient harm could be done which could have been avoided. This would be more consistent with the CMS requirement to perform verification prior to recipient organ removal in living donation if applicable.

We also agree with the final verification prior to transplant remaining for all deceased and living donor procedures. Timing language specifies that this verification must occur between the time the organ is delivered into the operating room and the first anastomosis to address transplant community questions. Language has been added to the proposal to include the transplanting surgeon as part of the process consistent with current CMS requirements.

We believe the policy proposal to be overly prescriptive and complex and the AST is not supportive of the policy as currently drafted. The complexity of the modifications have not been easy to follow in the proposed policy language. The policy needs to clearly outline requirements. Adding check-in and additional verification will not necessarily improve compliance with ABO policies. In view of the very low reported incidence of catastrophic outcome with an ABO incompatible transplant, we do not find it necessary to redesign the entire process.

For policy 5.6.A, table 5.1, we identified a couple of serious issues with this requirement as currently presented:

1. The policy requires the host OPO in conjunction with the onsite surgical recovery team to perform a deceased donor organ recovery verification which requires a recipient to be identified with unique qualifiers, a recipient blood type, and compatibility in addition to other elements. What process does the host OPO follow when the intended recipient is unknown while the onsite surgical recovery team and OPO are conducting the verification? This being a common occurrence with kidney allocation.
2. When the onsite surgical team is recovering an organ for another transplant center, how can the OPO and surgical recovery team perform the verification without having the required documentation? Is the onsite recovery team expected to take responsibility of verifying a potential recipient who is listed at another transplant center?

Proposal #14: [Proposed ABO Subtyping Consistency Policy Modifications](#)

Comments: The AST supports this policy change which will correct inconsistencies that currently exist in the OPTN policy and create an accurate standardized method to report ABO subtyping.

Proposal #15: [Proposal to Allow Non-Substantive Changes to the OPTN Policies and Bylaws](#)

Comments: The AST supports this proposal which mirrors similar models from other rule making bodies (namely legislatures and regulatory bodies). Many legislative and regulatory bodies have procedures that provide authority for making minor changes to their policies and legislation.

Proposal #16: [Proposal to Notify Patients Having an Extended Inactive Status](#)

Comments: The AST agrees that listed patients and their referring physicians/primary care providers should be kept well informed concerning the patient's status on the waiting list. However, rather than requiring notification at 90 days of inactivity followed by 365 days and annually, we would favor requiring a letter to be sent to the patient, referring physician, and primary care provider within 10 days of when the patient is made inactive, at 365 days, and then annually. This letter should provide the date the patient was made inactive, the reason for the inactivity, the fact that the patient will not receive organ offers while inactive and what needs to be accomplished to achieve active status on the waiting list. The letter should also include a phone number that the patient, referring physician, or primary care physician can call to report updates on the patient's condition or evaluation to the transplant program so that the period of inactivity can be as short as clinically necessary. Sending communication at the time of inactivation rather than at 90 days will make tracking of the need for initial documentation easier for the transplant program (i.e., it is related to the date of inactivation rather than requiring a reminder of some kind at 90 days) and will also provide more timely information to all concerned, even though it will result in an increased overall number of notifications. The written communication at 365 days and annually should include similar information.

We realize that the briefing document indicates that this alternative was considered but not pursued due to concerns that it would keep programs from inactivating patients for short periods of time leading to more patients not deemed currently transplantable appearing on the match run. However, the need to keep the patient informed and for programs to appropriately manage their waitlists based on the patient's actual transplant candidacy would seem to outweigh this concern.

We would also like to see a more clearly outlined plan for education and communication of this proposal to the transplant community in general and transplant coordinators in particular. Specifically, education regarding creating custom reports within UNet and the employment of Excel macros to assist with patient identification and communication at 365 days and annually as described by this policy should have a more defined plan other than "professional and patient resources" as these tools will help minimize the transplant coordinator work burden significantly. Additionally, we would like to see a better defined time course for TCC evaluation of this proposal, which is currently stated to be "a few years".

Proposal #17: [Proposal for Adolescent Classification Exception for Pediatric Lung Candidates](#)

Comments: The AST in general supports this proposal. However, there are two items of consideration that are not adequately addressed by the proposal:

1. Monitoring the effects of lobar transplants from adults into children under 12 with adolescent candidate exceptions. Since there is limited data supporting this approach for young children and size matching does seem to be critical to successful outcomes, the proposal for monitoring should specifically intend to evaluate this issue. Presently the proposal for monitoring post-transplant outcomes does not differentiate based on donor source i.e.; reduced lung or whole from small adolescent donor. We would request that UNOS provide data in two years that reports the impact of this change.
2. In putting forth this proposal, the UNOS Thoracic Committee did not document any alternative strategies that were considered prior to committing support to this proposal. Specifically, since we are unsure as to whether lobar transplants from adult donors into young children are the

safest choice, especially when the large majority of pediatric donor lungs currently go into adults, was consideration given to an alternative strategy such as expanded sharing of adolescent organs to pediatric candidates beyond the local zone (at least through zone A and preferably further) before offering those organs to adult candidates?