



American Society of Transplant Surgeons

December 5, 2013

Kenneth A. Andreoni, MD

President

Organ Procurement and Transplantation Network (OPTN)

United Network for Organ Sharing (UNOS)

700 North 4<sup>th</sup> Street

Richmond, VA 23219

Dear. Dr. Andreoni,

The American Society of Transplant Surgeons (ASTS) has reviewed and considered the following six proposals out for public comment through December 6, 2013.

Below is the Society's position on each proposal.

**Proposal #1: Proposal to Modify Deceased Donor Testing Requirements (Ad Hoc Disease Transmission Advisory Committee)**

ASTS supports this proposal aimed at promoting transplant patient safety through updated deceased donor screening requirements.

**Proposal #2: Proposed Histocompatibility Rewrite (Histocompatibility Committee)**

ASTS supports the overall goals of this proposal and defers to the American Society for Histocompatibility & Immunogenetics (ASHI) response for specific concerns. We share ASHI's concerns over the development and role of guidance documents. ASTS believes OPTN guidance documents should be evaluated with the same deliberative review as potential policy. In most cases, potential guidance documents should be subject to a public comment period 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, since many guidance documents have the potential to influence patient care, there may be topics for which a Joint Societies Work Group (JSWG) is appropriate prior to the public comment period.

**Proposal #3: Proposal to Establish Minimum Requirements for Living Liver Donor Follow-Up (Living Donor Committee)**

ASTS supports this proposal and thanks the committee for accepting the recommendations from the Joint Societies Work Group (JSWG).

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**Proposal #4: Proposal to Require UNet Registration of all Living Donor Organ Candidates Prior to Transplant (Living Donor Committee)**

ASTS supports this proposal that would require candidates for living donor transplants to be added to the waiting list before their transplant.

**Proposal #5: Proposal to Revise the Current Method for Flagging for Transplant Program Post-transplant Performance Reviews (Membership and Professional Services Committee (MPSC))**

ASTS does not support this proposal as currently written. While ASTS supports the Bayesian model as a sound method, we disagree with the hazard ratios, which were arbitrarily set to ensure the same number of programs that are currently flagged will be flagged in the new system. The proposal includes the thresholds to define flagging under the new system, which include: 1) The probability is greater than 75% that the hazard ratio is greater than 1.2, or 2) The probability is greater than 10% that the hazard ratio is greater than 2.5. It is time for us, as a community, to do better when it comes to the SRTR/OPTN flagging process. Instead of selecting a hazard ratio that ensures 1 of 8 programs ends up flagged, the community should better define what should trigger review by the OPTN Membership and Professional Standards Committee (MPSC) and set the ratios accordingly. It is our understanding that currently, the MPSC investigates all 100+ flagged programs and typically takes action on only 12-24 of them. If the switch to the Bayesian model were accompanied by more appropriate hazard ratios, MPSC could focus its work on the true under-performers. The current flagging system is often used in a manner that decreases transplant opportunities to patients in this country and thus decreases opportunities to utilize donated organs and allow patients with end stage organ failure to live longer. Transplant centers' fear of "the flag" can result in risk aversion and is counterproductive to our collective goal to increase the effectiveness and efficiency of organ transplantation. One potential solution is to create different thresholds for 'flagging' versus 'peer review.' For example, the MPSC could use the above thresholds to peer review a yet-to-be-determined number of programs over a certain period of time, and it could set a second threshold criterion that would 'flag' a smaller number of programs that more closely approximates the smaller number of programs a year that have any significant MPSC action, including a peer visit or higher action.

Currently, MPSC peer review is interpreted as a true negative program outcome, when in reality it is just the initial trigger for closer examination of the center's waitlist activity, policy procedures, QAPI program and outcomes. This summation of total program performance is the true evaluation of the patient's experience at a given transplant center and not simply a relatively minor outcome difference. This complete look at a program from its success of getting listed patients to transplant based on available organs to the program, the center's safety in policy and QAPI initiatives, and its outcomes is a better measure to examine transplant programs and decide if programs are adequately performing for their transplant candidates and recipients.

**Proposal #6: Proposed Patient Notification of Lack of Transplant Functional Inactivity (Membership and Professional Standards Committee (MPSC))**

ASTS does not support this proposal and appreciates the opportunity to comment on the proposed policy change that would require notification of listed patients when a defined period of transplant inactivity occurs at a given center. The intent is specifically to make patients aware of the program's inactivity and the availability of more active centers. The threshold of inactivity varies by organ: for heart, liver and kidney it is no transplants in 3 months and for pancreas and lung, 6 months. Recent UNOS analysis of a 3-year period (2010-2013) found that inactivity triggers are most often met in pancreas, with an average of 17 programs/year meeting an inactivity threshold, versus 1.6 for heart, 1 for kidney, .6 for lung, and .3 for liver. Thus, while the policy would apply to all organs, the discussion below is focused on pancreas as an illustrative example.

The proposal under consideration rests on the premises that such notification will: 1) encourage transfer of patients from lower to higher volume programs where they will receive superior care and/or 2) be a punitive measure that will spur low volume programs to become more aggressive and increase their transplant rate and volume. ASTS objects to the proposed policy based on the fact that neither premise is supported by data suggesting there will be a benefit to the patients involved and the fact that the policy could have negative consequences for patients and the field of pancreas transplantation in general.

Regarding the assumption that patient outcome will be improved by being transplanted at a high versus a low volume center, the OPTN/UNOS pancreas committee reviewed data on both post-transplant survival and the waitlist mortality at high and low volume programs, and in neither case was there a significant difference in outcome between low and high volume centers. If there is no expected benefit to the patients, we question why such a policy would be put forward to the OPTN board for consideration. Furthermore, a patient electing to transfer to a higher volume center with a higher transplant rate, while not gaining appreciable benefit, will suffer the confusion and inconvenience of transferring their care to another center that is likely farther away and detached from their existing network of care providers. This is particularly problematic for SPK patients who constitute the majority of pancreas recipients and who benefit from maintaining their ESRD care at a closer location.

We also contest the suggestion that the punitive nature of notifying patients of program inactivity will encourage more aggressive utilization. Surgeons and programs practice in a manner compatible with their abilities and risk aversion tolerance. To attempt to dictate patient care by forcing programs to accept organs and/or recipients that would otherwise have been declined may yield poorer outcomes for patients and programs and potentially lead to closure of what was previously a well-functioning low volume program. At a time when the field is already contracting with a >30% reduction in pancreas transplants in the last decade, unnecessary (with necessity defined by outcome) program closures will be the inevitable result of this proposal. This will likely reduce overall patient access to optimal care and lead to a further decline in total pancreas transplant volumes. For example, small centers evaluating diabetic patients for kidney transplantation who have lost their pancreas program may merely elect to list the patient for renal transplant rather than refer the patient to another center offering combined kidney-pancreas transplantation. In other cases, potential SPK candidates may prefer to stay at their current center to receive a kidney alone rather than confront the obstacles of relisting for SPK elsewhere (such as logistics, re-evaluation testing, added travel, etc).

We also question the claim in the background of the public comment proposal that the current levels of “inactivity are too low for a program to remain current with both surgical skills and programmatic administrative competence.” This assertion fails to consider the fact that most pancreas centers also perform renal transplantation and that there are largely overlapping skill sets in pancreas and kidney transplantation surgically, medically, and administratively. Thus a program performing only a handful of pancreas transplants per year may in part remain current through an active kidney transplant program. Other problems with the current proposal include: 1) that it fails to consider the correlation of regional variation in organ availability with the distribution of low volume centers, as well as how regional variations in wait time affect program inactivity, and 2) whether the planned changes in pancreas and kidney allocation that simultaneously prioritize pancreas transplantation and eliminate regional variances will affect the likelihood of program inactivity.

Low volume center conservatism in organ and recipient selection is likely multifactorial but almost certainly is motivated in part by an attempt to maintain excellent results. This notion was also evident in the minutes of the pancreas committee deliberations on the matter: “Committee members hypothesized that a relatively low number of quality donors in a given DSA could be a factor in this trend, compounded by a hesitancy to use less ideal organs knowing that a single poor outcome would result in a quality review of that program. This is not as much of a concern at higher volume centers because a single poor outcome will not have the same magnitude of impact on their actual versus expected outcomes metric.” We agree with this point and suggest that in the case of low volume activity, that OPTN/UNOS and SRTR analyses routinely consider a larger window of activity to relieve the performance pressure for low volume programs to minimize the chances of a single graft loss. This might serve to stimulate more liberal donor and recipient selection.

Finally, given that 70% of pancreas transplant programs perform 10 or fewer transplants/year, we suggest that UNOS reconsider the merits of their focus on yearly program volume for transplants of organs such as pancreas for which there exists a high percentage of low volume programs and no data to suggest that low volume in itself is a measure of program quality and patient outcome.

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,

A handwritten signature in black ink, reading "Alan Langnas". The signature is fluid and cursive, with the first name "Alan" and last name "Langnas" clearly distinguishable.

Alan N. Langnas, D.O.  
President