

American Society of Transplant Surgeons

August 18, 2014

Eileen Brewer, MD Chair, OPTN/UNOS Pediatric Transplantation Committee 700 North 4th Street Richmond, VA 23218

Re: OPTN Bylaws proposals – pediatric transplant training and experience

Dear Dr. Brewer:

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity for continued dialogue as the OPTN/UNOS Pediatric Transplant Committee considers bylaws aimed at distinguishing programs that perform pediatric transplants. As you know, ASTS first submitted feedback in July 2013 and then met with the committee via conference call on June 17, 2014. At the conclusion of the June 2014 call, ASTS was offered the opportunity to provide additional feedback and recommendations which are included in this communication. The enclosed feedback is based on a series of conference calls and email communications with a task force of ASTS members representing considerable expertise in pediatric transplantation and including Drs. Andre Dick, Jean Emond, Carlos Esquivel, Doug Farmer, Kishore Iyer, Charles Miller, Ron Shapiro, and Peter Stock.

ASTS is supportive of reasonable policy that positively impacts patient care and specifically pediatric transplant surgical care. After careful review of the revised bylaws proposal, ASTS is unable to support the recommendations in their current format. In an effort to help guide further deliberations, ASTS puts forward the following issues that should be examined in more detail prior to finalizing any policy proposal in this regard.

It remains unclear to us what "problem" the proposed bylaws are designed to address.

As noted in our previous communication, additional bylaws requirements should not be undertaken without clearly defined goals that address clearly identified problems. ASTS maintains that a survey of the community is necessary to identify the current landscape of pediatric transplant care delivery. More immediately, MPSC data related to pediatric program

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Executive Director Kimberly A. Gifford, MBA Kim.gifford@asts.org quality issues reported/reviewed and the frequency should help define the scope of the problem the proposal is designed to address. Greater clarity in this regard will help develop more nuanced and effective criteria.

ASTS is deeply concerned by the elimination of size stratification from the proposal.

It is our understanding that size stratification was eliminated based on feedback at the regional meetings. The ASTS executive committee and the task force identified above are unified in the belief that size stratification must be reinstated into the final proposal. A simple numbers requirement for pediatric cases in patients less than 18 y/o fails to capture the important differences in the level of expertise required for smaller children. For example, in pediatric kidney recipients, a surgeon leading a pediatric kidney transplant program should have experience in transplanting children under 25 kg, since this is the approximate cut-off at which the operation changes from an extraperitoneal operation to an intraperitoneal operation. The latter frequently involves cross clamping the abdominal aorta and inferior vena cava, in turn changing the dynamics of the operation, including the important interaction between experienced surgeons and pediatric anesthesiologists. For the liver and intestine, the technical challenges of transplanting a baby less than 6 kg are vastly different from transplanting a 15-year-old, though under current and proposed criteria, both are "pediatric." In the absence of specific data, we would suggest considering specific experience for the designated surgical head of a pediatric liver transplant program, represented by reasonable numbers in transplanting babies in each of 3 groups: from 0-1 year of age, from 1-5 years of age and > 5 years (or 5-18). Additionally, it is our strong opinion that demonstrated training and experience in performance of technical variant transplants and segmental grafts should be an essential component of "pediatric experience for program leadership." Given the small numbers of intestinal transplants being performed currently in a limited number of centers and given that close to 50% of current intestinal transplants occur as part of liver-containing grafts, extending the liver criteria as a proxy for pediatric intestine criteria may be a reasonable expedient at the present time.

The sole focus on numbers ignores key attributes of a successful pediatric program.

ASTS recognizes that there must be a minimum bar by which to judge programs. However, it is insufficient for numbers to be the sole criteria. Important aspects such as selection processes and outcomes must be included. If the goal of the proposed policy is to judge competency, then training, experience, numbers, weights, <u>and</u> outcomes are surrogates that must be considered en masse.

In conclusion, ASTS is grateful for the continued efforts of the OPTN/UNOS Pediatric Transplant Committee to create meaningful policy. In its current state, we believe there are key items that must be addressed prior to going forward with public comment. We understand that a newly formed Joint Society Work Group (JSWG) is examining surgeon/physician requirements and it is conceivable that this group will also consider pediatric requirements. If the pediatric issue is outside the scope of their task, we strongly urge the committee to convene a panel of pediatric transplant surgical experts to help set meaningful guidelines for size stratification. Given the position of the ASTS as the responsible body

charged with overseeing training of transplant surgeons, ASTS looks forward to the opportunity to continue these discussions with a shared goal to create meaningful pediatric transplant surgical requirements.

Thank you for the opportunity to participate in the discussions surrounding this very important issue. I look forward to speaking with the committee at its August 26, 2014, meeting via conference call.

Sincerely yours,

Peter G. Stock, MD, PhD

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