April 15, 2010

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President
Edward R. Garrity, MD
Chair, Policy Oversight Committee
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Re: Public Comment Concerning Proposed Modifications to Data Elements on Tiedi Forms (TCR, TRR, TRF, LDR, LDF) and Approval of a New Explant Pathology Form for All Liver Recipients

Dear OPTN/UNOS Board of Directors and Policy Oversight Committee,

The American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) recognize and acknowledge the work of the various OPTN/UNOS committees, including that of the Ad Hoc Data Management Group (AHDMG) and the Policy Oversight Committee (POC). We appreciate and welcome the opportunity to comment on the OPTN/UNOS proposal, and recognize that this is the first stage of a process mandated by the Office of Management and Budget, which mandates review of the OPTN data collection activities every three years. However, for the reasons set forth below, we request that no data elements be added at this time, subject to further study and consideration of our concerns, as set below.

A. Lack of Convincing Evidence of Predictive Value Relevant to Allocation Policy or Risk Adjustment

We have carefully reviewed the proposed modifications to the data elements and have a number of very serious concerns, which are set forth in detail (and which affect >98% of

the proposed data element additions) in the accompanying spreadsheet (Attachment A). Specifically, after an extensive clinical literature search and extensive internal and external discussions, we find little or no scientific support for the collection of the vast majority of the data elements proposed for inclusion for TCR, TRR, TRF, LDR, and LDF forms. Also, regarding the new explant pathology form for all liver recipients, we oppose the routine use of this form for all liver recipients since this would mean that transplant centers would be forced to provide negative data elements for the vast majority of liver recipients. We propose instead that the requirement for submission of this form should be limited to patients who had a MELD exception for HCC, those who had a pre-transplant diagnosis of HCC without a MELD exception score, and those found to have HCC on the explants.

The current proposal calls for the addition of a significant number of data elements that transplant centers will be mandated to collect and report to OPTN/UNOS. Yet the SRTR Technical Advisory Committee (S-TAC), in its report to the OPTN/UNOS Board of Directors in November 2009 (Attachment B) stated that there have been a number of studies demonstrating little improvement in the predictive power of the methodology despite the addition of numerous variables. In its report, the S-TAC concluded that additional variables should only be added if there is sufficient evidence to support their use. Their conclusions and recommendations agree with concerns voiced here. Unfortunately, nowhere in the S-TAC presentation was there mention of the guiding principles, which is especially disappointing given that some members of the S-TAC were also members of the UNOS team that developed and implemented the process by which the POC would monitor such data element requests. The S-TAC presentation (PowerPoint slide #30) raised the need for "pilot studies" to demonstrate the potential predictive power of new data elements, and recommended that OPTN/UNOS and SRTR "need to determine the resources required to achieve improved predictive ability (increased data collection, cost)" (slide #26). But research and pilot studies such as these should not result in an unfunded and mandatory increase in the number of data elements collected by all transplant centers. Instead, these efforts should be funded as separate research initiatives.

B. Failure to Apply the Guiding Principles

We are also extremely concerned that this proposal ignores important input and historical precedent from key stakeholders involved in past and present deliberations regarding the proposed modifications. In this regard, we are disappointed that the very committees within OPTN/UNOS whose charge it is to review each individual data element request in the context of previously agreed upon guiding principles, failed to apply those principles to the vast majority of the data elements now being requested.

As discussed in more detail below, after extensive discussions and deliberations, it was previously agreed that the POC would play a critical role in assuring that all data elements required to be reported be consistent with certain "guiding principles". In our view, however, it appears to have failed to meet its full responsibility. The POC seems to have provided inappropriate latitude to the organ-specific committees, while ignoring

input from the Transplant Administrators Committee. In addition, while the POC has raised the guiding principles in its deliberations, all too often it seems to not have strictly challenged these committees to adhere to them. We attribute these unfortunate developments to an apparent lack of institutional memory within the committees including the POC, and therefore we take this opportunity to remind the OPTN/UNOS Board about the history and context of the guiding principles that are so clearly alluded to, but so operationally ignored in the current proposal.

We would like to refresh your memory regarding the initial purpose of the Data Modification Initiative. It had become apparent after review of the thousands of data elements collected by, and submitted by transplant centers, that a significant number of these elements were incompletely and/or poorly collected due primarily to a lack of clarity in the definitions provided by OPTN/UNOS. Also, it was clear from this review that despite good intentions, members of various OPTN/UNOS committees had requested a growing number of data elements as a result of deliberations primarily intended to fulfill regulatory and oversight responsibilities of UNOS as a result of its OPTN contracts, including the requirement that OPTN/UNOS provide timely data to the SRTR for production of program-specific reports. These circumstances had led to a significant proliferation of data submission requirements for the centers, which, in the absence of any associated funding, had then, and have now become untenable and unsustainable. Therefore, after a significant amount of discussion within the transplant community, a set of guiding principles were developed by the AST and ASTS, presented to, and approved by the OPTN/UNOS Board in 2006.

Using the principles as a framework, the data improvement plan approved by the OPTN/UNOS Board was implemented. Although the final outcome of this exercise was not entirely consistent with the AST/ASTS recommendations (Attachment C), the data improvement plan was implemented largely intact. Another factor that spurred the development and implementation of the data modification initiative was the fact that CMS regulations now mandate 95% compliance with collection and submission of these data elements, with punitive consequences associated with non-compliance.

As a result of the data improvement initiative, it was agreed that the POC would approve any new data requests that came up through the various committees, and that the POC would use the principles to guide the decision to approve or disapprove even the most attractive requests in an effort to prevent the expected proliferation of requests from the other OPTN/UNOS committees. Although there was not complete agreement by OPTN/UNOS with the guiding principles submitted by AST/ASTS, there was, in our opinion, an understanding that any request for new data submissions would be approved by the POC only if it was necessary to: 1) develop policy and regulations to allocate organs for transplant; 2) determine if transplant centers were complying with OPTN policy; 3) determine program-specific compliance; or 4) assure patient safety where no alternative data exist.

C. <u>Cardiovascular Risk Factors</u>

An important element in the discussion consists of the fact that CMS and commercial payors use the program-specific reports generated by the SRTR under its contract with HRSA as a "bright-line test" for certification of transplant centers to receive reimbursement for the provision of transplant services. We and others have repeatedly made the case that SRTR-generated program-specific reports should be used for review and remediation purposes rather than for certification decisions. This has raised issues regarding the risk-adjustment methodologies used by the SRTR as well as by data elements that would be required for optimal risk-adjustment. With these issues in mind, ASTS has previously asked that certain co-morbidities, primarily cardiovascular risk factors shown to be predictive of poor outcome, be included in the risk-adjustment models. However, in the same communication to OPTN/UNOS (Attachment D), we reiterated our dissatisfaction with the use of program-specific reports for certification decision-making. We also suggested that if these reports were to continue to be used in this way, that improved risk-adjustment would be needed. While we admittedly emphasized the need for better cardiac risk stratification, our comments should be viewed in the context of our previous and current opposition to the use of OPTN data collection process for research purposes First, data collection and submission resources of transplant centers cannot be taxed in an unlimited and unregulated fashion in attempts to formulate potential risk-predictors. Any "research" that is needed to identify these risk-predictors should be funded and not simply turned into yet another unfunded mandate. Second, any risk-predictor that is added to the list of required data elements should have been proven to indeed be a significant risk-predictor worthy of collection and submission by the transplant centers consistent with the guiding principles. Our previous letter should therefore not be viewed as a "blank check" to OPTN/UNOS to conduct otherwise unfunded research. The transplant centers should not be viewed as sponsors for such research.

In order to determine which cardiovascular risk factors should be analyzed in the ***kidney transplant*** population, UNOS assembled an "Expert Panel" of cardiologists and nephrologists to make recommendations. Unfortunately, material in appendix B, which accompanied the public policy proposal, provides no clarity regarding how the expert panel reached conclusions, using scientific evidence, supporting the inclusion of these data elements. It is difficult for the societies to support the inclusion of these data elements without understanding the weight of the evidence behind the expert panel's recommendations. A better method of providing this information would either be the creation of a white paper or better, a peer-reviewed publication so that the weight of the scientific evidence can clearly be elucidated. The societies would be interested in further dialogue with HRSA and the OPTN regarding review of cardiovascular risk adjustment in kidney transplantation.

More specifically, certain data elements related to cardiovascular risk were supported only moderately or not at all by the convened "Expert Panel". Yet the POC chose to include these in the data element request. The most notable of these are atrial fibrillation and sleep apnea. Also, although the "Expert Panel" supported the use of cardiac troponin as a predictive factor, it should be pointed out that the limited data which has been published by the Mayo group and which formed the basis for their support has not been

externally validated by other groups. Also, the assay used by the Mayo group is not currently in use at other institutions and the sensitivity of the assay may affect its specificity. Moreover, there is currently a sense within the cardiac community that the cardiac troponin level may be more useful in conjunction with other markers, particularly markers for heart failure. Despite these preliminary data on patients with ESRD and those either awaiting or following kidney transplantation, no data whatsoever exist to warrant the use of cardiac troponin in non-renal patients. Further, appendix B. states specifically that the OPTN and HRSA "undertook a process to develop recommendations for cardiovascular related data elements to be collected on *kidney transplant* candidates and recipients (italics added)" . Unfortunately, it appears that the POC and the organ specific committees added these cardiac risks factors to all organs despite the panel's tasking to develop cardiovascular risk factors for kidney transplantation. Given these shortcomings, it would seem prudent to await further validation before prematurely incorporating cardiac troponin in solid organ transplant risk-adjustment models.

Finally, it was interesting to note that for both ejection fraction and cardiac troponin, transplant centers are given the opportunity to record that the test was not done, and therefore the data for these particular elements are not available. It should be clear from previous experience to both the Board and the POC that this loophole will almost certainly result in a high level of data "missingness" that is likely to render any analysis of submitted data not interpretable. The corollary to this is that transplant centers should not, and cannot be mandated to obtain these tests if they are not part of their existing practice, especially in the absence of compelling and convincing evidence that they are truly predictive of poor outcomes.

Therefore, despite our collective desire to improve cardiac risk-adjustment, we believe that OPTN/UNOS does not provide enough information about the process and rationale used by the expert panel to come up with their decision and therefore we cannot support inclusion of these data elements at this time.

D. New Liver Explant Form

Regarding the use of the new liver explant pathology report for patients undergoing liver transplantation, we believe that the requirement for submission of this form should be limited to patients who had a MELD exception for HCC, those who had a pre-transplant diagnosis of HCC without a MELD exception score, and those found to have HCC on the explants. Sufficient diagnosis fields should be provided to record multiple diagnoses, when present, rather than the current limitation of two.

E. Compliance with OMB Clearance Processes

Finally, we note that the timetable set forth in the Proposal fails to take into account the time necessary for OMB clearance. The Proposal appears to suggest that the changes will become effective 30 days after Board approval.

However, it is our understanding that the Proposal is subject to Paperwork Reduction Act requirements. Under the Paperwork Reduction Act, agencies must publish proposed information collection in the Federal Register for a sixty-day public comment period. After reviewing the public comments and revising the proposed collection as appropriate, agencies submit the proposal to OMB for review, discussion, and approval. Once obtained, approval must be renewed every three years. In order to obtain or renew such approval, OMB Form 83-I must be attached and filed with the Office of Information and Regulatory Affairs (OIRA). Form 83-I must explain the reason why the form is needed and estimate the burden in terms of time and money that the form will impose upon persons required to fill it out. In the case of the additional data required to be reported under the Proposal, that burden is extremely significant, and strict compliance with Paperwork Reduction Act requirements is critical.

In this regard, we have significant concerns that the OPTN/SRTR has minimized the burden of data entry on transplant centers. For example, Roberts et al. (Cost of OPTN Data Collection for a Larger Transplant Center *AJT* 2003; 3:1316-1317) compared their institutional (UCSF) findings to UNOS' ICR estimates of the burden involved for transplant centers. While UNOS predicted 1755 hours/year of effort based on UCSF volume, the actual effort at Roberts' institution was 2.46 FTE, or 5117 hours (2080 hours/year). The UNOS estimate of cost burden in 2007 dollars for an institution with this volume would be $40,374, whereas 1999-2001 actual average annual cost was $143,025, or $172,776 in inflation adjusted 2007 dollars, suggesting a three to four fold error in the OPTN/UNOS estimate used to seek OMB approval of the forms. Furthermore, Roberts et al. used direct costs only and did not include indirect costs in their analyses, suggesting that the degree of underestimation is likely higher than we have demonstrated. While this analysis may suffer from certain assumptions about inflation and the use of single-center data with potential geographic cost variances, this important study provides clear evidence that the OPTN/UNOS may grossly underestimate the cost of the data burden on transplant centers. Therefore, we propose that, prior to seeking OMB approval for any modifications in data elements, the OPTN/UNOS work with transplant centers to obtain more realistic estimates of cost burden of the proposed modifications.

Also, regarding the fact that certain modifications consist of "deletions" or simple "modifications" a brief survey of the additions, deletions, and modifications demonstrates a strong net increase in reporting effort given that most of the "deletions" are technical and do not currently require much effort, whereas the added elements are associated with significant effort. Therefore, any analysis of cost burden should take an "activity-based cost accounting" approach in order to fully assess the net impact of form modification on the transplant centers.

It is particularly troublesome that, in addition to underestimating the cost burden, the OPTN/UNOS provided justification for the burden that was neither supported by evidence, nor consistent with authority granted them under federal contract. As one example, their submission stated that "timeliness of post-transplant data collection is essential to advancing organ transplantation policy and science." Yet they do not cite

any evidence to support this, nor do they cite any authority to impose a reporting burden for so vague a purpose as "advancing policy and science." It is surprising that the OMB accepted this without further substantiation, and it is our expectation that the Proposal will be subject to a more rigorous analysis under the Paperwork Reduction Act.

Therefore, prior to approval of the current proposal, we would like some assurance that the proposal will be compliant with OMB requirements with regards to timeline, assessment of cost burden to the transplant centers and finally specifying the authority that justifies the proposal.

Conclusion

In summary, the AST and ASTS appreciate the opportunity to offer a detailed analysis of the requested data elements as part of the public comment process. We emphasize the need to consider the previously approved process and guiding principles, not as a perfunctory piece of the process, but as an important and essential filter designed to avoid the proliferation of well-intentioned data element requests by the various OPTN/UNOS committees as they pursue the primary objective of improving the field of transplantation and the care of both living donors and transplant recipients. We reiterate the notion that transplant centers should not become the funding source for clinical outcomes research in search of potential risk predictors. That said we fully support the collection and submission by transplant centers of data elements proven to be risk predictors, for inclusion in risk-adjustment models used for program-specific reports. We would also like to reduce the potential for data collection that will inevitably result in non-interpretable analyses given the loophole (in the current proposal) that would allow for transplant centers to simply claim that the test was not done, and therefore the data are not available. In this context, we strongly advise the OPTN/UNOS Board against mandating specific tests as "standard-of-care" medical practice, especially where there is a lack of compelling and convincing evidence to support their routine use.

Therefore, in view of this detailed and informed analysis, <u>we strongly oppose the request for added data elements to TCR, TRR, TRF, LDR, LDF forms. Given that other data element modifications are tied to these requests, we also oppose the other proposed modifications.</u> We urge the OPTN/UNOS Board of Directors to abide by their previous resolve to minimize the data and cost burden to transplant centers and to limit approval of individual data element requests to those that strictly meet the previously agreed upon principles. We also urge the OPTN/UNOS Board to put into place the necessary structure, or to reinforce the existing structure, so that transplant centers are not repeatedly faced with unreasonable, unsupported, and unfunded requests for data collection and submission.

We propose that HRSA, OPTN/UNOS and the SRTR convene a task force, composed of the key stakeholders to address the issue of funding for the type of outcomes research which is foreshadowed by the current proposal. Specific to cardiac risk stratification for kidney transplant recipients, we propose that a process be established with some urgency that is inclusive of all stakeholders and that the evidence base, process and rationale for

the inclusion of new data elements be defined and transparent so that better risk-stratification can be effected and implemented. In addition to addressing the predictive value of defined variables, we should also examine the consequences of performing transplants on recipients at higher risk of poor outcomes. We should strive to explore potential sources of funding for the type of research that will ultimately allow the transplant community to optimize transplant outcomes. The AST and the ASTS would be happy to participate in such an initiative, and we look forward to the invitation.

Sincerely,

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