American Society of Transplant Surgeons

Saving and improving lives with transplantation.

ASTS Responses to UNOS Proposals Open for Public Comment

March 23, 2018

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1. Aligning VCA Program Membership Requirements with Other Programs

The American Society of Transplant Surgeons vascularized composite allograft (VCA) committee reviewed this proposal and provided significant input into the Society's response. ASTS recognizes that the purpose of the proposal is to align VCA primary surgeon requirements with those of other transplant programs. In general, we caution OPTN to not create a burdensome regulatory environment that proceeds the clinical environment. While this field is still in its infancy, we don't want to stifle innovation or ongoing research. In response to the policy proposal, the Committee considers this it is an unusual circumstance for any transplant program to have a primary surgeon without recognized board certification in surgery, and strongly recommends that such programs are regularly monitored by the MPSC.

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2. Modifications to the Distribution of Deceased Donor Lungs

The American Society of Transplant Surgeons thoracic committee reviewed this proposal and provided significant input into the ASTS response. ASTS supports this proposal overall; however, the Society has concerns over the 250 nautical miles as the first unit of distribution and is concerned that the 250 nautical miles wasn't made with sufficient assessment. While this change may help certain centers, it will have unintended consequences and harm other (smaller) centers. ASTS remains concerned that travel and acquisition costs might increase. This aspect should be monitored, and we would like to see one-year review data.

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3. Clarify Informed Consent Policies for Transmittable Disease Risk

The American Society of Transplant Surgeons appreciates the opportunity to comment on the current OPTN/UNOS Public Comment Proposal to Clarify Informed Consent Policy for Transmittable Conditions.The ASTS commends the Ad Hoc Disease Transmission Advisory Committee (DTAC) for addressing this critical issue that has direct impact on transplant candidate education, acceptance decisions for donor organ offers, informed consent processes, patient follow-up requirements, and transplant center workload. In addition, clarification of the relevant policies related to donor-derived transmissible disease risk has implications on the regulatory burden carried by transplant centers and the UNOS Membership and Professional Standards Committee (MPSC).

The ASTS supports the proposed changes to OPTN/UNOS Policies 15.3, 15.3.A, and 15.3.B as written, with specific comments detailed below:

1. The reorganization of the language in policy 15.3 and 15.3.A to fit with the timeline that patients experience from transplant evaluation, to listing, to transplant, is an important evolution in this policy. The ASTS strongly supports the general concept of robust pre-transplant (e.g. pre-listing) education about the low but real risk of donor-derived disease transmission. The creation of standardized and patient-focused education tools, as exemplified the recent Joint Working Group Guidance document regarding PHS increased risk donors, is an important part of this effort. Provider-focused education, such that donor-derived disease transmission risks are accurately conveyed to patients, is also critically important.
2. The ASTS largely supports the changes made to policy 15.3.B, and as detailed in Table 15-1, to clarify specific consent requirements related to donor-derived transmissible disease risk that require specific consent at the time of transplant. The linking of specific pre-transplant consent requirements to existing *Policy 5.3.B Infectious Disease Screening Criteria* is sensible and requires specific consent for organ-specific criteria that drive offers received by individuals on specific match runs.
3. The ASTS acknowledges that the intention of this effort by DTAC, and the current public comment proposal, was not intended to address the requirement for specific pre-transplant consent for organs from a donor at increased risk for transmitting HIV, hepatitis B, or hepatitis C as specified in the U.S. Public Health Service (PHS) guidelines. The ASTS position on this requirement is detailed below.

The public comment proposal posed two specific additional questions, and the ASTS response is summarized below:

1. *Should informed consent policy include an actual patient signature or is discussion and medical record documentation sufficient?*

   The ASTS supports a distinction between education processes and materials provided prior to transplant listing, and pre-transplant consent. For pre-listing education, transplant centers should maintain robust education processes (written materials, formal education classes, and provider discussion) that emphasize the possibility of donor-derived disease transmission. Patient participation in these programs should be documented in the medical record as part of the pre-transplant education process that occurs prior to transplant listing.

   In the case of pre-transplant consent for donors with risk identified pre-transplant, as detailed in the revisions to policy 15.3.B and Table 15-1, the ASTS believes it is reasonable to require patients to provide specific written informed consent, as these details are characteristics of an organ on a specific match run for an individual component. In many transplant centers, this may occur as an additional line item on consent forms for the transplant procedure that requires patient signature or initials (for example, patients signing to receive an organ from a donor with hepatitis C, hepatitis B, or from a donor that meets PHS increased risk criteria).

2. *Do you have any concerns or comments about the list of conditions in the current candidate screening (Policy 5.3.B Infectious Disease Screening Criteria) and re-execute the match (5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results) policies?*

   The ASTS supports this parsimonious list of donor conditions that affect candidate screening and execution of the match run, as they are directly linked to patient's access to organs from specific donors. Patients may be listed as eligible to receive (or not receive) organs from donors with these specific infections, which may have a profound impact on waitlist outcomes. The ASTS believes it is then reasonable to require specific pre-transplant consent for these conditions, and further the ASTS believe that this establishes a principle that could allow sensible changes to consent requirements for as screening policy changes (for example as treatments for specific infections evolve and improve).

Finally, although the ASTS strongly supports the efforts of OPTN/UNOS to clarify consent policy for donor-derived transmissible disease, we believe that the current efforts should be viewed as a first step in a larger effort to refine consent requirements

for transplant candidates. As a first principle, the ASTS believes that informed consent policy requirements should be proportional to the risks posed to patients. Requiring specific pre-transplant consent for organs from donors that meet PHS increased risk criteria, which pose an overall risk of disease transmission of approximately 1 in 3000, while not requiring specific consent for donor characteristics that directly affect organ quality (donor age, comorbid disease, organ-specific conditions) and have far greater impact on graft and patient survival, gives patients the inevitable impression that the risk of donor-derived risk transmission is "more important" or of "greater risk" than these other more common and influential donor and organ characteristics.

Furthermore, the ASTS strongly supports, to the degree possible, removing specific consent requirements from the time of organ offer (pre-transplant consent). Transplant centers must inform patients of the uncertainties inherent in solid organ transplantation, and the small but real risks of donor-derived disease transmission. Transplant centers must maintain robust pre-transplant education processes and materials that should be continuously revised and updated to accurately reflect the best estimates of disease risk transmission, post-transplant surveillance requirements, and the implications of disease transmission on graft and patient survival. However, requiring specific consent for rare events (e.g. disease transmission from a donor that meets PHS increased risk criteria) at the time of transplant is misleading to patients and has been shown to decrease offer acceptance, which may be associated with increased waitlist mortality. Even in the best hands, consent obtained from patients at the time of organ offer (which may occur at odd hours with very ill patients who are overwhelmed with the prospect of finally receiving a transplant) may be poorly understood and retained, disproportionately alarming, and seemingly coercive. The ASTS strongly supports therefore removing consent requirements from the time of transplant for rare events, such as donor-derived disease transmission, in favor of strengthening pre-listing education processes to aid transplant candidates in understanding these important concepts.

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4. Concept Paper on Expedited Organ Placement

The American Society of Transplant Surgeons appreciates the opportunity to comment on the concept document on expedited placement for hard-to-place allografts. The ASTS strongly supports the desire to improve the efficiency of organ placement, reduce organ discard, and increase the number of transplants performed. As time to placement increases, ischemic time and the risk of discard increase. We strongly endorse rigorous tracking of acceptance behavior to avoid offering organs to centers that never use organs with certain risk factors.

Eventually this data will inform allocation of organs and streamline placement. We support the development of pilot projects to achieve expedited placement among interested centers. These might include automatic expedited placement using data-derived filters, center-based allocation, or inversion of the waiting list, as proposed by Dr. Ratner, “dealing from the bottom of the deck.”

We recognize the concern that some centers might “lose out” on offers based on their own past behavior and a system should be developed to increase offers to those centers based on expectations of increased acceptance using defined filters.

Ultimately the system will encourage and support centers that wish to expand their filters and increase utilization.

1. Should an allocation system include an expedited placement trigger based on defined donor characteristics that would allow an OPO to expedite the placement of an organ?

The development of a decision tool which identifies hard-to-place organs and triggers an alternative placement methodology is logical. This requires pre-recovery allocation to prevent late reallocation, which must become the exception and trigger quality review. This trigger may also be used to adjust the number of different centers that are offered the organ simultaneously to increase placement. As more centers gain experience with these organs, centers will be given the opportunity to change their acceptance practices and regain access to donors with risk criteria.

2. Should an allocation system include an expedited placement trigger based on an event like an organ declined in the OR that would allow an OPO to expedite the placement of an organ?

We support the use of intraoperative turndowns as a trigger for expedited placement of donor organs as intraoperative turndowns dramatically increase the risk of discard. Additional triggers including the need for expedited recovery due to hemodynamic instability could also be considered.

All intraoperative turndowns should be subject to QAPI activities at the level of the center and the OPO. Each time an organ is declined, the center should be asked to explain what data was available at recovery but not prior to that time (e.g., liver biopsy, abnormal anatomy) that led to this decision. Decline for quality after cross clamp dramatically increases the risk of organ discard. Centers which repeatedly engage in this practice should be encouraged to participate in process improvement activities.

3. Should the allocation system allow an OPO to move to an expedited list after a well-defined point in the allocation process (e.g., after offers to x candidates, after offers to x hospitals, within x hours of the scheduled OR time)?

We support other triggers to move to an expedited placement as appropriate. Once the donor is in the room, expedited placement is appropriate in the case of intraoperative turndown or expedited recovery for hemodynamic instability. In this case, cross clamp should be delayed pending final allocation of all extra renal organs if possible.

4. Once an expedited placement trigger has been met, should the OPO use their own discretion to get the organ placed for transplantation?

The ASTS supports the use of structured, policy-driven allocation decisions, that will incentivize OPO's to maximize placement of organs. The use of OPO discretion to bypass potential candidates to offer the organ to known aggressive centers reflects a failure of the current system that should be improved. The expedited organ placement system should include an opt-in feature (similar to high KDPI organ acceptance). However, if centers choose to opt in to the system and then repeatedly decline offers that are accepted by other candidates, they will be excluded from the expedited offer program until they demonstrate a plan to change their practice.

5. Once the expedited placement trigger has been met, should the list of potential candidates be limited to those at transplant hospitals with a recent history of transplanting organs from similar donors?

The organ allocation process must be fair and transparent. The use of extended criteria organ is contingent on having appropriate candidates on the list and institutional capabilities to care for similar transplant recipient/donor selection. The expedited organ placement system should include an opt-in feature (similar to high KDPI organ acceptance).

Transplant programs should have the option to opt into the expedited placement system. Centers must look objectively at the benefits for their patients. In addition, patients who indicate a willingness to accept higher risk organs should be informed about the center's use of higher donor risk organs. Patients should also be provided with data on transplant rate and outcomes which will allow them to make an informed choice about accepting high risk donor organs.

6. Should transplant hospitals be allowed to choose whether or not they want to have their candidates on an expedited list?

Transplant programs should have the option to opt into the expedited placement system.

7. Should the allocation system give higher priority to candidates more likely to accept an organ that has a higher likelihood of discard based on statistical models?

As acceptance data improves, allocation will be informed by past behavior as in many other system algorithms. Patients should be included in the alternative

allocation system on an opt-in basis and ordered using standard allocation parameters. Models that identify hard-to-place organs might be used to determine the number of initial offers that are made and should be used to initiate the expedited system.

8. Should DonorNet® set a transplant hospital's acceptance criteria based on the hospital's past acceptance practices?

Yes. However, centers should have the opportunity to set their own *DonorNet®* criteria and receive feedback about their acceptance practices. If centers repeatedly decline organs which are accepted by other centers and for which a willing listed patient exists, they should be engaged in a process improvement intervention such as the COIIN project. Centers that continue to decline appropriate offers should be subject to additional review by the OPTN and MPSC.

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5. Reduce Reporting Burdens and Clarify Policies on Extra Vessels

The American Society of Transplant Surgeons supports this proposal as written.

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6. Guidance on Optimizing VCA Recovery from Deceased Donors

The American Society of Transplant Surgeons vascularized composite allograft committee reviewed this proposal on behalf of the ASTS executive committee and was supportive of the guidance document as written.

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7. Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests

The American Society of Transplant Surgeons thoracic committee reviewed this proposal on behalf of the ASTS executive committee and recommended support of the proposal as written.

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8. Changes to Waiting Time Criteria for Kidney Pancreas Candidates Involving Maximum Allowable BMI

The American Society of Transplant Surgeons believes that a maximum BMI represents unnecessary regulation and recommends the elimination of BMI limits for kidney/pancreas transplant.

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9. Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function Following Transplantation

The American Society of Transplant Surgeons thoracic committee reviewed this proposal on behalf of the ASTS executive committee and does not think it is useful to collect bronchial stricture data. ASTS believes the question should be removed.

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10. Revising OPTN Bylaws Appendix L

The American Society of Transplant Surgeons applauds the efforts by UNOS and the MPSC in attempting to streamline some of the most arduous processes transplant centers have to face, namely MPSC inquiries. We also appreciate the time and effort put into the process which is clear throughout the document. The ASTS also acknowledges the need for a transparent, robust review system that maintains public trust, promotes safety in transplantation, and is objective and fair.

Unfortunately, MPSC oversight has over the past few years been viewed by transplant programs and professionals as a major regulatory hurdle that is costly, time consuming, and with marginal impact on advancing the field. We doubt that the new proposal will be viewed by our membership as a significant advance, as it falls short of our membership expectations of real regulatory relief that would help advance the field.

In the new proposal, a fair amount of detail has been removed regarding potential actions to be taken by the MPSC against a given program under investigation. Considering the history of MPSC oversight, a deficit in this level of detail increases the chance of subjective interpretation and leaves potential actions and subsequent monitoring subject to individualized interpretation by the MPSC members. Of particular concern is the subjectivity of determining imminent threat to the health of the public, particularly in a discipline as complex as transplantation. Similar to the original version, it is clearly stated (now multiple times in the new document) that the burden of proof is on the program to “prove that the MPSC’s recommendation lacks substantial basis or the conclusions drawn are arbitrary, unreasonable, or capricious.” This is an extremely high bar for any Transplant Center and, at its root, is unfair because the MPSC acts as the investigator and prosecutor in making the allegation and then acts as judge and jury, rendering the recommendation for punishment. We believe that this conflict must be addressed to restore the trust of the community in the process.

Considering that the basis of an MPSC action is not well defined, and the interpretation of its severity and impact on safety is all subjective, a program can be accused of virtually any potential violation/noncompliance at any time, and the vague tone of the revised Appendix L leaves programs at a potential disadvantage in this

setting. Of special concern is that the term “due process” has been removed from the title page and that the new format introduces an informal discussion format, which considering the subjectivity of the process can be detrimental to programs’ due process down the line.

Specific concerns and suggestions to improve the document

Besides the overall concern over the direction of this document, we are providing more specific concerns that illustrate some of the difficulty with the amended version.

> L.5 Investigation of potential noncompliance with OPTN obligations. When the OPTN becomes aware of a member’s potential noncompliance with OPTN obligations, the OPTN will conduct an investigation. This investigation will evaluate whether a potential noncompliance exists. The investigation will also consider whether the potential noncompliance suggests a risk to patient health or public safety, and the urgency and severity of the risk.
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> Members must respond to all investigation requests within the specified period. A member may provide any information that it believes relevant to the investigation. The OPTN will notify the member of the date by which the member must submit the requested or additional information.

Comment/concern: At present, any written correspondence between the MPSC and the program may or may not detail the nature of the exact violation/noncompliance. We feel that the OPTN should clearly state the nature of the potential non-compliance to be investigated. The member may then provide the most relevant information to the OPTN related to any questions of non-compliance with membership requirements or professional standards. In addition, this level of detail should be restated on each correspondence thereafter. This will alleviate any confusion by the program as to why the correspondence is occurring in the first place.

> L8. Informal discussion. An informal discussion is a direct conversation between a group of MPSC members and a member currently under MPSC review. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. Informal discussions are information-gathering activities that may lead to a more efficient and effective review than written correspondence and document reviews alone.

Comment/concern: Any correspondence between a program and the MPSC, either written, by phone, or in person, should be considered “formal.” This should be relabeled to reflect the seriousness of the situation. Perhaps “Initial” discussion.

L8. E. Informal discussion format.
Informal discussions will be conducted by teleconference and will include:

1. At least 10 minutes for the member to present information.
2. At least 15 minutes for the member to respond to questions from the MPSC.
3. At least 4 MPSC members.

Comment/concern: Depending on the exact nature of the potential violation/noncompliance, 10 minutes is likely not enough time to adequately cover a specific case in question, program policy/procedure, and/or administrative issue being discussed.

L9. Interviews.

L9. C. Interview format.
Interviews may be conducted by teleconference or at an in-person MPSC meeting, as determined by the MPSC Chair. Interviews will include:

1. At least 15 minutes for the member to present information.
2. At least 30 minutes for the member to respond to questions from the MPSC.
3. At least 10 MPSC members.

At least 2 of the 10 MPSC members must have expertise in the organ of specific issue that is the subject of review. If there are not at least 2 subject matter experts available from the MPSC, the MPSC chair will select individuals with the appropriate expertise from other OPTN committees. These individuals may participate in all aspects of the interview process, but they serve in an advisory role and do not have a vote.

Comment/concern: This section is especially troubling with regard to potentially complex surgical cases such as heart transplant, high MELD liver transplant, and/or dual organ cases. In our opinion, 2 experts may not be adequate. Furthermore, the current document assumes this expertise will be present within the OPTN committees itself. While that may be true for some unknown fraction of cases, the current revision leaves no room for the program to provide its own experts, in addition to OPTN, which may help clarify and/or reinforce certain clinical standards of practice, surgical decision-making, and the current state of a given discipline. Giving programs the ability to have an outside clinician, with a robust practice, the opportunity to review specific issues would be extremely helpful in certain circumstances regardless of the ultimate outcome. As result, we feel that the OPTN should consider a policy where members can bring their own experts forward in either interviews or hearings.

L10. Hearings.

L10. C Hearing format.
At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue that is the subject of review……

Comment/concern: Again, given the seriousness of any potential violation/noncompliance, the current document stops short of what is needed. See above. However, this issue now becomes extremely important as the process progresses. At the level of a hearing, in addition to legal representation, a program may not be able to adequately defend its position to the MPSC if the appropriate amount of experience with the matter is not present.

L11. Appearances before the Board of Directors.

L11. D. Board of Directors appearances format.

Comment/concern: In general, it is concerning that waiving a right to a hearing automatically waives the right to appear before the Board of Directors. More importantly, the order of the proceedings in front of the Board of Directors becomes important for the program in question. Given that the burden of proof is on the program, the MPSC chair should be first to present the information stating and reinforcing the noncompliance against a program. Forcing a program to present information first, followed by the MPSC, puts the program at a sizable disadvantage.

L12. OPTN Actions.

L12.A. Deferred disposition.
The member is not entitled to an informal discussion, interview, hearing, or Board of Directors appearance to challenge the MPSC's decision to not offer or to end a Deferred Disposition period.

Comment/concern. Again, this puts all programs at a distinct disadvantage. At the very least, a program should have the right to a "Formal Discussion" with the MPSC which outlines (in detail) the reasons for not offering or ending a Deferred Disposition period.

L12.B. Types of actions.

Comment/concern: Within the amended Appendix L, a letter of reprimand has been removed. This is concerning as it creates a fast track to probation or member not in good standing.

L.12.D.1. Probation monitoring requirements.

The MPSC will monitor members throughout the Probation period.

Comment/concern: This section is vague. Programs should have a clear view of what ongoing monitoring actually means. For example, what information will be required by the program and at what time intervals? Does the probation period require site visitation? If so, how many? At what time intervals?

Appendix L: Original Version.

L6. Requests for root cause analysis and corrective action plan

Comment/concern: This section was very helpful in terms of what the program can expect.

L15. D. MPSC actions without board referral.

Comment/concern: Letter of reprimand has been removed. See L.12.B above.

L15.E.1. Probation.

Comment/concern: Again, at least a broad description of Corrective Action Requirements of Probation can be helpful to the program in question.

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11. White Paper on the Manipulation of the Waitlist Priority of the Organ Allocation System Through the Escalation of Medical Therapies

The American Society of Transplant Surgeons ethics committee reviewed this proposal on behalf of the ASTS executive committee and provided this response. ASTS supports the work that OPTN has done to acknowledge that waitlist manipulation occurs and to bring this discussion forward in the form of a white paper. We believe that providing care for the sole purpose of increasing prioritization on a waiting list is inappropriate, reprehensible and is not to be condoned - one patient's increased priority is at the expense of another patient's prioritization. ASTS , however, also makes note that OPTN allocation policy that many physicians feel they need to, or can, manipulate is a policy that likely needs refinement. Allocation policies should, as best as possible, reflect objective criteria that are readily reproducible and least manipulatable, even when done in the spirit of helping an individual patient.

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12. Guidance for ABO Subtyping of Blood Type A and AB Organ Donors

The American Society of Transplant Surgeons supports this proposal which has improved blood typing and is vital to safely perform Non-A1 to B and O transplants. This guidance document should be adopted by all OPOs to ensure that patients are safely and accurately blood typed.

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13. Concept Paper on Improving the OPTN UNOS Committee Structure

The American Society of Transplant Surgeons supports the goal of efficient management of the OPTN through improved member engagement. As noted in the concept document, OPTN is in a fortunate position that a broad group of stakeholders wish to be involved in the policy development processes and we commend OPTN for exploring novel pathways for expanded member participation. ASTS believes OPTN should have the flexibility to try innovative approaches to member engagement and efficient policy development. Recent examples demonstrate that the current model is lacking. During the comment period, we have heard from several constituencies that the proposed model may leave some focus areas such as pediatrics and infectious disease under-represented in important policy discussions. Specifically, the ASTS pediatric task force expressed concern that a change to an expert panel (instead of committee) would significantly limit the pediatric community's ability to initiate and present OPTN/UNOS policy proposals, which would negatively impact the outcomes of their patients and the welfare of their community. At the same time, the current committee structure is broken as the required regional representation can result in gaps in expertise on the committee. This unique population needs formal representation and appropriate expertise. We encourage OPTN to work in conjunction with its membership to account for these concerns as they finalize a new structure for member engagement.

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14. Guidance on Requested Deceased Donor Information

The American Society of Transplant Surgeons supports the proposal to allow the request of additional donor information prior to organ acceptance. This guidance document lays out suggested criteria for additional diagnostic evaluation. The committee should consider a more extensive evaluation of processes to allow communication of the results of this information. For example, the use of telepathology to allow capture and presentation of donor histology as simply including the biopsy material or slide with the organ is not sufficient. In addition, clearer definitions are need. For example, what defines acute kidney injury. For pre-procurement liver biopsy, many OPOs refuse requests for pre-recovery biopsies in multiorgan donors. This leads to logistical complications, necessitates reallocation, and increases organ decline which would be avoided should the OPOs adhere to

these guidelines. OPTN must carefully balance additional information against additional delays in organ placement. Additionally, ASTS always cautions that guidance documents have been previously adopted as de facto policy by payers and OPTN should always be aware of this unintended consequence of guidance documents**.**

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15. 2018-2021 OPTN/UNOS Strategic Plan

Strategic planning is an important governance activity and we commend OPTN for the deliberative approach taken to identify goals, news initiatives, and key metrics. The American Society of Transplant Surgeons strongly supports the primary goal to increase the number of transplants. Regarding goal #2, to provide equity in access to transplant, ASTS hopes that lessons learned from past allocation discussions will allow for a more efficient process in the future. Regarding goal #3, improve waitlisted patient, living donor, and transplant recipient outcomes, we note that some initiatives are difficult to measure (e.g. improve longevity of organ transplants) and may be outside the scope of OPTN's ability to influence. For goal #4, promote living donor and transplant recipient safety, we encourage OPTN to continue to work with CMS to reduce duplicative processes and regulatory burden on transplant centers. We strongly support the proposed knowledge sharing about safety events and effective practices across the community. Finally, for goal #5, promote efficiency in donation and transplant, we applaud OPTN for focusing on efficient policy development and IT enhancement to support the overall system. Additionally, we encourage OPTN/UNOS to reevaluate the core values outlined within the document. Core values should reflect the fundamental beliefs of the organization and help differentiate between right and wrong and aid in decision-making.