



## **American Society of Transplant Surgeons (ASTS) Statement of Principles: OPTN Modernization Initiative**

- We support efforts to improve and modernize the operations of the Organ Procurement and Transplantation Network (OPTN) to better serve transplant candidates, recipients, donors, and recipient and donor families. ASTS strives to improve the health of those who suffer from organ failure and may benefit from the life-saving gift that comes from organ donors and their families.
- OPTN modernization efforts should prioritize changes needed to remove barriers and increase candidate access to transplantation. Improving equity in access to transplantation for historically disadvantaged populations must be a priority.
- We propose the following Statement of Principles as examples of how we can enhance OPTN functions that work well and correct those that do not, to learn from the past and plan for the future. These Principles are presented by addressing mission and purpose, authority and governance, access and equity, operations (including transition), and transparency of data.

### **The Modernized OPTN's Role in Establishing National Goals and Improving Coordination Among Public and Private Stakeholders**

- OPTN modernization must be geared to increase access and drive improvements in equity in transplantation, both of which require close coordination of all public and private entities directly related to the transplant process. Public entities that should be involved include not only HRSA and its contractors (the OPTN and SRTR), but also the Centers for Medicare and Medicaid Services (CMS), which exercises regulatory oversight over transplant programs and organ procurement organizations (OPOs); the Food and Drug Administration (FDA), whose processes impact the availability of new immunosuppressants, diagnostics, and therapeutics; and the National Institutes of Health (NIH), the primary source of transplant research funding are also critical stakeholders that would benefit from better integration with HRSA.
- The active and continued voluntary participation of transplant professionals, professional associations, patient and donor groups, OPOs, and others is critical to improve access and equity in transplantation, and the ability of those stakeholders to participate in the process and to be heard by regulators will be important for ensuring the success of a reformed and revised transplant ecosystem.
- To restore and ensure the public's trust in the system, it is imperative that all stakeholders' voices be considered not only through "response to comments", but also in appropriate fora that need to be made available for deliberation, discussion and debate.

- Those who make final decisions must be provided with the authority and resources to ensure that those decisions are implemented as intended if they are to be held accountable by regulators for the subsequent impact of any action taken.
- There is an immediate and pressing need to institute the changes necessary to improve access and equity. As recommended by the National Academy of Sciences, Engineering and Medicine in its report entitled, [\*Realizing the Promise of Equity in the Organ Transplantation System\*](#) (2022), the first step in achieving these objectives is to develop national performance goals and associated metrics for the U.S. organ transplantation system and a National Strategy that identifies specific proposed requirements, regulations, payment structures, and other changes necessary to reduce disparities and increase access.
- The National Strategy should include an action plan:
  - to improve coordination among the various agencies with authority over different aspects of the organ acquisition, allocation and transplantation processes and between governmental agencies and the public;
  - to objectively assess system performance and identify gaps that inhibit optimum performance;
  - to eliminate current disincentives to transplantation, including social determinants of health; and
  - to improve system efficiencies.
- The OPTN should be reconceptualized as the instigator and overseer of coordinated efforts to improve the transplant process for patients and their families and as the platform to monitor progress and keep improvement efforts on track. Specifically, as a public/private partnership, a modernized OPTN should bring together all stakeholders to draft the National Transplant Strategic Plan and establish an ongoing process that includes all federal policymakers and key stakeholders to implement the plan.
- The OPTN can and should prioritize access to living donor organ transplantation and reduce disparities in this area. The OPTN should work with its members to disseminate living donor best practices and with patient groups to address the needs and concerns of living donors and their families. In addition, the OPTN should ensure that allocation algorithms give appropriate priority to living donors in need of a transplant and make any policy changes needed to enable the gift of life by altruistic donors to be magnified by utilizing altruistic donor organs in paired kidney exchange to the extent practicable. The OPTN should identify barriers to living donor transplantation, especially for medically underserved populations and work with federal agencies to mitigate the lack of alignment in federal programs and goals with respect to living donor transplantation.

### **OPTN Governance and Authority**

- OPTN Membership should include patients, donors, transplant centers, OPOs and other transplant stakeholders as determined by the OPTN Board of Directors (“Board”) to ensure that

experience, expertise, and knowledge from content experts, especially those who care for patients in need of transplantation, form the basis for all assessments and decisions. The OPTN should remain a non-profit membership organization.

- The OPTN should remain the entity that establishes policies related to organ acquisition and allocation and takes such other action as may be necessary to carry out the functions delegated to the OPTN under the National Organ Transplantation Act (NOTA) and the Final Rule.
- The OPTN legal entity should operate independently and should engage in no activity other than the operation of the OPTN. Moreover, OPTN staff and officers should not be engaged in providing transplant-related services to any other for-profit or not-for-profit entity.
- The OPTN should function as a Board-driven organization, which requires a more streamlined Board composition.
  - While NOTA and the Final Rule impose OPTN Board composition requirements, these requirements should be fulfilled by establishing a modernized OPTN Board that does not exceed twenty Board members.
  - The modernized OPTN Board should review the current OPTN Committees, Bylaws, and Policies and Procedures. Streamlining the OPTN organizational structure and processes will improve the timeliness of statistical modeling, significantly accelerate policy implementation, and enforce a culture of accountability.
  - New and revised Bylaws and Policies and Procedures should be established by the Board, as the Board determines necessary to achieve these objectives.
- The OPTN should remain solely responsible for assessing and collecting registration fees from member organizations, and these registration fees should be utilized for the purpose of performing the functions delegated to the OPTN under NOTA and the Final Rule. The OPTN Board should retain the authority to determine how patient registration fees are spent for the purposes of performing the functions outlined in NOTA and the Final Rule.
- The OPTN should develop a formalized process and structure for consideration of stakeholder feedback prior to publication of a proposed new policy for public comment. A mechanism should be instituted that ensures that decisions made, or actions are taken by the Board are well-informed and supported by data.
- The OPTN should establish a mechanism for members and other potentially affected stakeholders to participate in a pre-implementation assessment of the operational issues and potential unintended consequences of any major proposed policy change, and such pre-implementation assessment should be considered by the Board in determining whether the change should be adopted.
- The OPTN Board should establish a mechanism for stakeholders to participate in monitoring the results of any major policy change that is implemented and for making any necessary modifications to mitigate adverse consequences.

- The OPTN Board of Directors should be elected by OPTN members, and the Nominating Committee should be broadly representative of the Board membership. A mechanism should be established for open nomination of Board members.
- OPTN staff, including the Chief Executive Officer, should serve as neutral arbiters of Board policy and should not attempt to sway policy directions or priorities of the Board or any Committee.

### **OPTN Priorities: Focus on Access and Equity**

- The modernized OPTN should focus on addressing access to transplantation and reducing disparities. Seventeen patients per day die waiting for a kidney and ten more patients are added to the list each day. Other objectives should take a “back seat” to addressing the urgent need to assist patients in gaining access to transplant.
- The modernized OPTN should quickly prioritize efforts to identify organ procurement, allocation or other policies, procedures or requirements that inadvertently impede the efficient procurement, allocation, and transplantation of transplantable organs and modify or eliminate any such policies, procedures, or requirements.
- The modernized OPTN should immediately establish a Task Force that clearly identifies barriers to access for historically underserved populations and proposes specific policy changes to address those barriers, with a focus on reducing disparities in living donor transplant access and increased acceptance of underserved populations who meet transplant criteria on transplant waitlists.
- The modernized OPTN should recognize that transplant centers are required to comply with comprehensive CMS regulatory requirements and should ensure that there is no dual oversight. Rather than duplicating CMS efforts in areas of practice already regulated under transplant program conditions of participation, the OPTN should focus its attention on providing education materials, best practices, and other resources necessary for transplant centers to increase the number of clinically appropriate transplants performed and to address disparities in access.
- A dedicated focus on improving organ utilization for hard-to-place organs is urgently needed. The modernized OPTN should assess the impact of allocation policies on utilization of hard-to-place organs as soon as possible and expeditiously make such modifications as may be necessary to increase utilization of these organs.
- The objective of peer review processes conducted by the OPTN should be to spread best practices and improve performance. Peer review processes should be confidential, non-punitive, and non-legalistic.
- Any OPTN committee that is charged with conducting peer review of transplant program should focus primarily on providing guidance to transplant programs with conservative organ acceptance criteria on safe and effective ways to increase the number of clinically appropriate transplants performed.

- Transplant center peer review criteria focused on one-year outcomes and three-year outcomes, which have been shown to disincentivize the utilization of hard-to-place organs, should be eliminated or significantly revised. Instead, peer review processes should be focused on optimal utilization of organs, maximizing aggregate life-years saved (in part by decreasing waiting times), decreasing disparities and waste, while achieving acceptable and properly risk-adjusted (especially on the recipient side) graft and patient outcomes.
- The modernized OPTN should assess whether and to what extent the payment policies of governmental and non-governmental payers inhibit access to transplantation, and especially access to new technologies intended to increase the number or quality of organs suitable for transplantation.

### **OPTN Operations**

- The OPTN should directly employ an Executive Director and such additional staff as may be necessary to ensure that the policies approved by the OPTN Board of Directors are carried out expeditiously and as intended by the Board and to support such committees as may be established by the Board. However, if the Board determines that some operational functions necessary to support the OPTN should be performed by a contractor, the OPTN should establish a mechanism for periodic monitoring and assessment of the contractor’s performance and a mechanism to withhold OPTN payment to the if contractors’ performance is suboptimal.
- All contractors engaged by HRSA to perform specialized OPTN functions should report to the OPTN Board. HRSA’s role is to ensure that the OPTN Board functions in compliance with NOTA and the Final Rule and to ensure that all HRSA contractors comply with OPTN Board directives.
- We appreciate that HRSA plans to enter into contracts with entities that may or may not have expertise in transplantation in order to make “best in class” Information Technology (IT) and other specialized services available to the OPTN.
- All HRSA contractors should be required to enter into a cooperative agreement with the OPTN as a condition of obtaining a HRSA contract to ensure that the activities of the contractor(s) are responsive to the policy and other decisions made by the OPTN Board and that the HRSA contractor activities are integrated into OPTN operations seamlessly with maximum coordination. Each cooperative agreement should specifically:
  - detail the process to be used by the contractor to communicate with the OPTN and other HRSA contractors;
  - designate a single individual or designated group of individuals responsible for coordinating the contractor’s activities with those of the OPTN and other HRSA contractors;
  - set forth schedule of performance assessments;
  - set forth contractor performance benchmarks;
  - provide a mechanism for resolving disputes;
  - establish a mechanism for the OPTN to review the contractor’s performance; and
  - provide that the contractor will not seek renewal of its HRSA contract without consultation with the OPTN

- The cooperative agreement of any HRSA contractor whose fees are paid in whole or in part by the OPTN should include a provision authorizing the withholding of fees for performance that does not meet OPTN expectations, thereby holding the contractor(s) accountable. HRSA contractors should not be authorized to charge OPTN members for their services.
- Prior to the renewal of any OPTN contract, HRSA should consult with the OPTN Board regarding the contractor's performance and any needed changes to the contractor's scope of work.
- To minimize the potential for lapses in coordination and to facilitate expeditious implementation of improvements approved by the OPTN to increase access and improve equity, HRSA should engage a separate contractor only if specialized expertise is needed and should engage a manageable number of controlled and targeted contractors.

### **Transition Issues**

- It is critical that OPTN operations, especially UNet, remain fully functional and operating without change or reduction in resources throughout the transition, including testing and implementation of any new matching system, to ensure that life-saving transplants continue to be performed.
- While key UNOS personnel should continue to be temporarily retained during the transition period to provide training to any new IT contractor engaged by CMS to operate UNet, their responsibility and authority should be limited to that of training others. Similarly, while UNOS should remain under contract with HRSA to provide training to transition contractor personnel for other critical UNOS functions to be specifically identified in the Transition PWS, they should not participate in a governance function.
- UNet and any new IT system used for matching donors and recipients should be operated in parallel to ensure that the new and current system results are the compatible.
- Allocation policy changes that have not been incorporated into UNet by current organ specific UNOS committees should be placed on hold and reassessed when HRSA selects a Next Gen Contractor to ensure that allocation policies take full advantage of new IT capabilities.
- During the transition, OPTN members should be consulted regarding the composition and size of the new OPTN Board, and nominations for Board membership should be solicited from OPTN members.
- While the current OPTN Board should continue to serve through the end of the transition contract(s), revisions should be made to their level of authority, and the new OPTN Board should be identified and prepared to assume responsibility for OPTN operations by the conclusion of the transition.

## Data and Transparency

- New and continuing OPTN data collection activities should comply with the following principles:
  - Data collection should be clearly tied to, and necessary for the achievement of, a clearly stated goal or objective that is one of the National Transplantation Goals.
  - New data collection should be authorized only if the data is unavailable from any existing data source.
  - Transplant centers should not be responsible for new data collection requirements unless funding sources outside the transplant centers are identified.
  - Every attempt should be made to automate clinical data submission by centers directly from EHRs and this should lead to efforts by SRTR to provide better risk-adjustment methodologies.
  - The appropriate audience for the data should be clearly identified and consulted about the utility of the proposed data collection before data collection is instituted.
  - The potential inadvertent repercussions of data dissemination should be thoroughly considered in advance.
- HRSA and CMS should collaborate to establish a single, comprehensive public-facing integrated website that provides educational information to candidates, waitlisted patients, recipients, donors, and donor and recipient families regarding transplantation, including data collected from SRTR to help guide candidates choosing a transplant center.
- The risk-adjusted transplant program-specific outcomes data required to be included on the SRTR website under the Final Rule should be presented in the context of comparison to outcomes of alternative forms of treatment for that specific end-organ disease process.
- Any public metrics that are established should focus primarily on encouraging optimal utilization of organs, maximizing aggregate life-years saved including decreasing waiting times, decreasing disparities and waste, while providing patients with easy-to-understand risk adjusted outcomes data.
- The outcomes metrics used under the current five- star rating system for transplant programs should be eliminated. This rating system strongly disincentivizes transplant programs from utilizing hard-to-place organs and does not predict future outcomes. The current system is severely flawed methodologically and therefore grossly misinforms potential recipients.
- Public-facing data should be responsive to patients expressed need for use friendly information that provide them with an accurate approximation of whether they are likely to meet a transplant program's waitlist candidate criteria and how long they are likely to remain on the waitlist and the impact on survival, considering the selected transplant program's historical performance for patients with similar demographic, clinical, and other profiles.
- Data collected to facilitate transplant center quality improvement and self-improvement should be clearly distinguished from public-facing data and should be shared with transplant programs

on a confidential basis.

- Data utilized by OPTN Committees and the Board for the purposes of assessing or modifying OPTN policies, including allocation policy changes, should be shared with stakeholders in a user-friendly format prior to Board or Committee review of such data and prior to deliberations utilizing those data.
- The role of the SRTR in data analysis and dissemination should be clearly defined and distinguished from the data-related role(s) of the OPTN and a written document should be drafted to outline each entity's responsibilities and role with respect to data dissemination to the public. Historically, the suggestions of the SRTR contractor are often accepted for implementation by the committees without to help assess the analyses provided by the SRTR contractor for the OPTN.