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Title: Organ Procurement and Transplantation Network (OPTN)

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Response From: American Society of Transplantation
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Via E-mail: NNazawa@hrsa.gov

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RE: OPTN RFI Response (NAICS Code: 541611)

On behalf of the American Society of Transplantation (AST), representing over 4,000 medical professionals engaged in the field of solid organ transplantation, we applaud your leadership and continuous efforts to improve the nation's organ donation and transplant system. We welcome the opportunity to respond to this request for information.

Overall, we believe that there is much to be done to align U.S. transplant system goals. We believe that the misalignment of incentives (patient outcomes and financial) must be reduced and stakeholders (e.g., OPTN, CMS and other payors, OPOs, and transplant programs) must exit siloes to work together effectively to make meaningful change. Common goals of increased organ utilization, increased transplantation, improved equity in access to and outcomes from transplantation need to be broken down into clear pathways for measurable success.

The AST provides the following comments for consideration. The AST does not intend to supply a proposal on any future solicitation related to this requirement.

A. OPTN Technology – IT System

A.1. Describe how you would/a vendor would implement and utilize modern IT architecture to:

a. Manage, track and operationalize the OPTN organ donation, procurement, allocation and transplant system, such as by adopting a “cloud-native,” agile, and modular approach to IT development and maintenance

The recent National Academy of Science, Engineering and Medicine (NASSEM) report suggests that the OPTN/HRSA should reevaluate paths to modernize the current IT architecture and data collection process in advance of the rebid process for the OPTN contract (i.e., deciding whether to separate the IT and policy/oversight contracts). This is absent from this RFI. We believe this is a critical element and recommend a delay on contract bidding if this cannot be completed in a timely manner.

The OPTN system should leverage existing electronic health records (EHR) and registry application programming interfaces (API) to enhance modeling in multiple domains (survival models, organ acceptance models, potential donor models, etc.) by accessing

this existing data to evaluate additional model variables and therefore reduce the cost of and time required to complete prospective data collection for this purpose.

System redundancy to prevent catastrophic failure is critical. We recognize value in both on-site and cloud-based redundant storage to protect the integrity of the system. Protected health information requires careful safeguarding. The system is complex, holding hundreds if not thousands of data elements for both donors and potential recipients that must be sifted through rapidly to generate appropriate match runs for consideration. The system is a long-term repository that tracks data for living donors and organ recipients. It cannot fail. It cannot be down for maintenance. A modular approach that will allow for rapid programming modifications (which also require extensive testing before launch) of a smaller segment of the system seems ideal in this situation.

b. Prioritize the use of publicly accessible application programming interfaces (APIs) to enhance data sharing and integration with the electronic health records (EHRs) and other tools used by OPTN members and patients.

It is critical that the application interfaces with EHRs accurately, effectively, and efficiently to avoid manual data transition to the donor, candidate, and recipient records. This leads to errors that can cause discard or even harm if not recognized and addressed.

Linkage to EHRs would enable innovation to improve system performance. For example, the use of artificial intelligence (AI) approaches to identify potential deceased donors admitted to hospitals rapidly with a high level of accuracy. Additionally, the addition of interfaces to collect patient-reported information will be important in advancing the capabilities of the system as patient reported outcomes (PROs) become an increasingly important element of patient care. Leveraging technology in this area will help facilitate patient engagement and increased patient monitoring between in person visits.

c. Enhance user interfaces to improve the ability of the OPTN IT system to conduct enhanced real-time tracking of donated organs, allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions.

This is a critical element. Real time tracking and allocation with transparency to transplant centers and waitlisted patients would significantly improve the processes, organ acceptance and ultimately patient survival. We can see our Amazon or Fed Ex packages move across the country in greater detail than we can this precious and critical gift of life.

d. Produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance.

We are supportive of the continued development and enhancement of performance dashboards to support program improvement. We are unaware of evidence linking public reporting to improved system performance and support generation of evidence to inform the optimal use of public reporting. We are not convinced that efforts to increase

transparency without specific and detailed education for the general public would be appropriate or valuable and would caution against potential unintended consequences.

e. Maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

Effective APIs to EHRs and other relevant data sources reduce opportunity for transcription error and unnecessary time and expense related to manual data submission. Automation of identification and referral of potential donors would be expected to increase the number of potential organ donors for evaluation.

Leveraging virtual technology to facilitate real-time communication between OPOs and transplant programs evaluating potential donors is critical. While COVID has forced increased comfort with telemedicine practices, we must harness these advances in organ donation and transplantation.

The use of virtual technology to facilitate timely evaluation of transplant candidates that would also facilitate standardization of the candidate evaluation processes between centers should be considered.

A.2 The current contract requires system availability uptime of 99.5%. HRSA is planning to target a 99.999% uptime for this lifesaving OPTN IT system. Is 99.999% uptime reasonable and achievable? If not, what is an appropriate uptime standard for an IT system of this importance?

The potential impact on patient lives necessitates the system uptime requirement be as high as reasonably achievable. This contract should also define the maximum downtime allowed during a single event for the purpose of requiring effective contingency plans that would protect system operations during a catastrophe.

A.3. How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?

Effective APIs with EHRs to avoid data transcription errors and periodic auditing of data are critical.

Timely audit of recovered but non-utilized organs by an independent entity should be supported by the system. Such an entity could then inform data elements (both donor and recipient) that are required to ensure that every safely transplantable organ is utilized for transplantation.

A.4. How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?

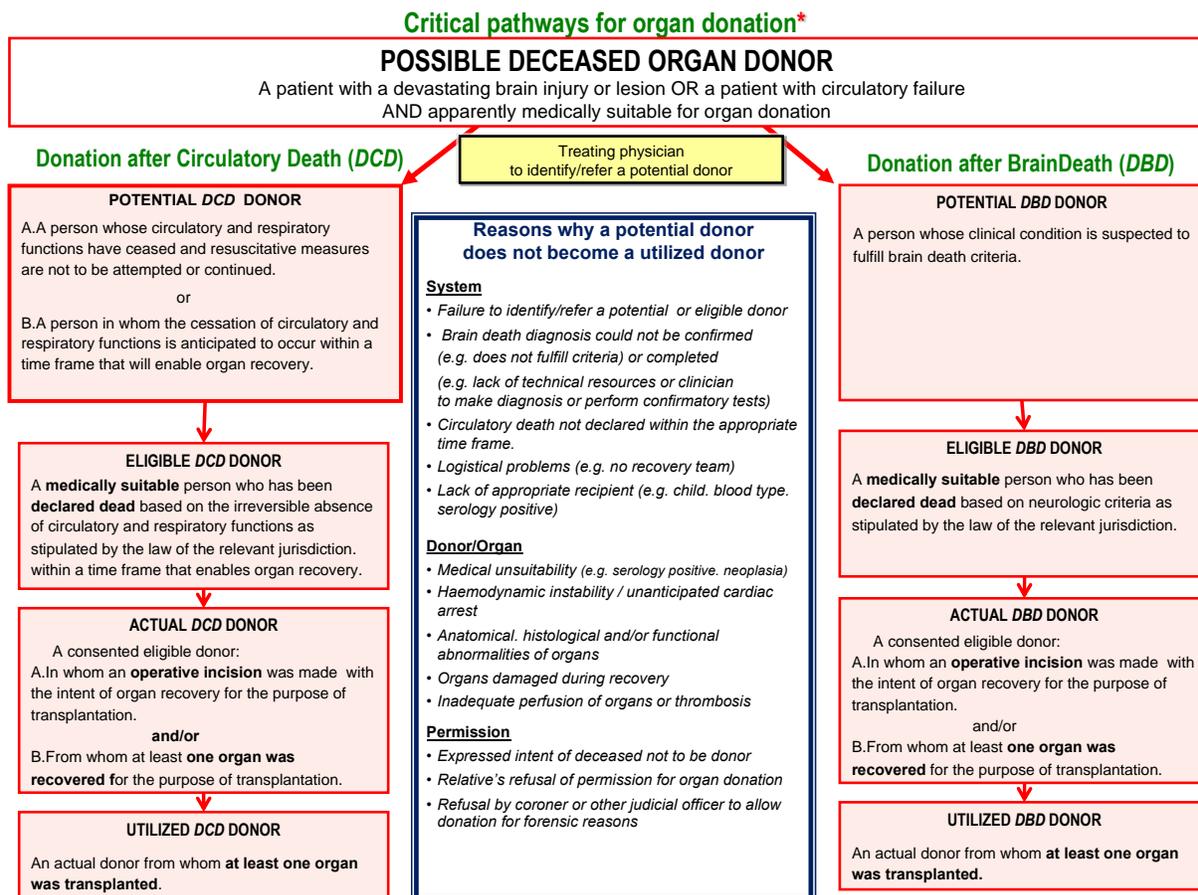
A.5. How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?

B. Data Collection Activities

B.1. Describe how you would/how vendors could develop performance metrics and

benchmarks for the organ donation, procurement, allocation and transplant system, including through expert consultation, subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value.

Organ Donation: There are established international metrics to monitor the proficiency of the deceased organ donation system (see figure below; reference- Transplant International 2011; 24: 373–378.). These metrics are predicated on accurate identification of potential donors admitted to hospital. AI approaches to identify potential donors through imaging and data already captured in EHRs should be advanced so that valid metrics that are dependent on accurate identification of potential donors can be produced. AI based approaches should be supplemented by periodic chart reviews which are the gold standard for identification of potential donors.



*The "dead donor rule" must be respected. That is, patients may only become donors after death, and the recovery of organs must not cause a donor's death.

Allocation: Timely audits of organ allocation to determine deviations from established algorithms and accurate determination of the reason for non-utilization of organs should be performed.

Organ allocation strategies that incorporate candidate preferences should be explored. As per previous comment, we do not believe real time consultation with waiting list candidates about organ allocation offers is feasible. However, advancement of aggregate metrics of center level practices regarding acceptance of organ offers could be considered. Periodic interactions with

wait-list candidates to review their transplant options should be supported to ensure organ acceptance practices are medically appropriate are aligned with patients' preferences.

B.2. Describe how you would/how vendors could structure data collection and reporting mechanisms for the system:

a. To report OPTN performance metrics including process, outcome, and patient engagement measures.

In the past 10 years, the value of data integrity has become recognized as a key to demonstrating the success of transplantation at each transplant program. Data entered on the Candidate Registration TIEDI form, such as ethnicity and pre transplant diagnosis, follows the patient through the various phases of transplantation. Organ procurement coordinators enter data about the deceased donor for patients that is then used in the SRTR analysis of each program.

Almost all transplant centers now have at least one data coordinator to manage data entry and analysis; however, the standards for these positions vary with each center. How are those entering data educated on terminology such as cold ischemic time, DCD, race and ethnicity? Many of these terms are within the SRTR Risk adjustment models and staff entering these data must be trained on how to accurately capture and report the data. In partnership with transplant centers and OPOs, the OPTN should recommend minimal standards for data personnel since the quality and integrity of this role in donation and transplantation is so powerfully impactful on outcomes.

Similar to the points made above, even a robust training program and supremely qualified staff will not completely eliminate data discrepancies as human error is intrinsic to manual data entry. HRSA should create incentives – either through the OPTN contract or otherwise – for EHR vendors, OPOs, and transplant hospitals to develop and maintain interfaces with UNetSM and the OPTN data system to minimize the need for manual data entry.

b. To establish OPTN member performance benchmarks.

c. To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors.

Allowing the opportunity for self-reporting of this type of data into the system may add an opportunity to gain efficiency in a small part of data collection and could be reviewed as part of the evaluation process or meeting with pre-transplant coordinator. It would be important to make this easily accessible by cell phone or tablet and have limited free text options, focusing on pull downs or multiple-choice fields.

d. To create public OPTN national, regional and local performance dashboards.

Publicly available data dashboards will need to be easily understood and explained. There may be merit in having separate resources for professionals versus public or even layered data where you could click through to drill down into more detailed data.

- e. **To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.**

Patient-reported outcomes will be a valuable addition here. It will be important to incorporate APIs that allow for input of this type of information from cell phones or tablets

C. OPTN Finances

C.1. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others:

- a. **Do not duplicate Medicare payment or result in unnecessary additional Medicare reimbursement.**
- b. **Do not charge for functions that are OPTN contract-supported functions.**
- c. **Are not perceived as mandatory for participation in the OPTN or for receiving core OPTN services.**
- d. **Do not impact, or create a perception of impact, status in or allocations through the OPTN.**

C.2. What requirements and oversight mechanisms could be utilized to ensure appropriate federal review of the OPTN registration fee, any additional contractor fees, and the development of the overall OPTN budget?

D. OPTN Governance

D.1. Describe how you would/how vendors could structure, finance and staff an OPTN board of directors independent of membership of the OPTN operational contractor's board of directors.

It is important that OPTN Board members can fulfil their fiduciary responsibilities to the OPTN, which may not necessarily align with the OPTN contractor's interests. Although we recognize that separating the Boards may assist in that regard, doing so will remove some of the influence the OPTN Board may have on the OPTN contractor. Moreover, a potentially significant conflict of interest that is not addressed in this RFI relates to the OPTN contractor executive director serving as the OPTN executive director. As these issues are intertwined with the need to improve the OPTN policy development process, we recommend that evaluation of the Board structures (independent vs. dual purpose, size, representation, etc.) as well as OPTN executive director COI be incorporated into the overall evaluation of the OPTN policy development process by an outside organization such as the NQF as mentioned in NASEM recommendation

D.2. Describe the conflict of interest policies you would/vendors could implement to ensure independence of the OPTN board of directors.

See above comments about OPTN executive director conflict of interest.

D.3. Describe the reporting mechanisms you would/vendors could utilize to hold operational contractors' accountable for system performance and outcomes.

D.4. Describe the additional factors and process steps you would/vendors could take to ensure effective operations of such an independent board of directors.

E. Increasing Organ Donation and Improving Procurement

E.1. Describe how you would/how vendors could support the OPTN in revising OPTN policy requirements for OPOs to reduce variations in practices and procedures, facilitate increased organ donation and improved procurement, and otherwise improve OPO performance.

In the current state It is unclear how the OPTN will have sufficient oversight of OPOs to make meaningful change. OPOs are primarily accountable to CMS. In contrast to transplant programs for which the OPTN can request that the HHS Secretary remove the designated transplant program status, the OPTN bylaws do not have a clear mechanism by which the OPTN Board can recommend to the HHS Secretary that an OPO lose its designation as an OPO for a given DSA. Moreover, any change in OPTN policy requirements pertaining to OPO member performance will not be automatically reflected in CMS conditions of participation. To achieve increased organ donation and improved procurement, shared OPO oversight and aligned accountability between the OPTN and CMS must occur. Finally, we recommend that the OPTN develop policies that incentivize collaborative efforts between OPOs and transplant centers to improve organ donation, procurement, and utilization.

E.2. How could the OPTN facilitate OPO engagement in research protocols to improve procurement?

Support training of OPO staff to acquire skills to conduct and support research and provide financial support for research.

E.3. What additional research could contribute to improving organ procurement?

AI approaches to identify potential deceased donors in hospitals. Evaluate public acceptance of centralized deceased organ donation. Financial support for research.

E.4. How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

The AST's recent [response to the February 2022 CMS RFI](#) and the NASEM report both emphasize the importance of increasing access to the waiting list and expanding the oversight of the OPTN to address this gap. We were surprised at the limited attention given to this topic within this RFI outside of this section. We believe that making advances in this area will have the greatest impact of any of the equity-related recommendations from NASEM or the RFI.

Advancement of programs to provide culturally sensitive support for deceased donor families should be considered. The availability of organ donation personnel with cultural sensitivity training and or language skills to optimally support deceased donor families by telehealth could be considered.

F. Organ Usage

F.1. Describe how you would/a vendor could support the OPO performance improvement activities to decrease discarded organs and further increase the use of organs.

HRSA should require the OPTN to incorporate strategies into OPTN Policy that incentivize innovation and usage of novel technologies to encourage greater usage of increased risk organs. Lessons from the Collaborative Innovation and Improvement Network (COIIN) - that strong partnerships between transplant centers and OPOs and adjustment of oversight to foster innovation lead to increased use of otherwise difficult to place organs – should be built upon and leveraged more expansively across the system. For example, and as alluded to in E.2, novel protocols to utilize specific measures (e.g., in vivo/ex vivo machine perfusion) in high-risk organs could be implemented by transplant centers in collaboration with OPOs.

F.2. How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?

Support a work group to develop implement and evaluate novel strategies to increase utilization.

F.3. Describe the steps you would/vendors could take to improve transparency around the organ matching and acceptance process for transplant candidates, transplant recipients, other affected patients, organ donors and family members served by the OPTN.

The AST would happy to participate in a working group to advance a strategy to increase transparency on this complex issue.

G. OPTN Operations and Policy Development Improvements

G.1. Describe how you would/vendors could incorporate, to the full extent permitted under applicable law, the NASEM report’s recommendations on increasing racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing OPTN policies.

We suggest ‘mandates’ or at minimum board policy commitments to increase diversity on boards/committees, such as a certain percentage of underrepresented minorities, women, etc.

G.2. Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables.

As outlined in NASEM Recommendation 2 (Improve the Organ Procurement and Transplantation Network (OPTN) policy-making process) we recommend that HRSA require the OPTN contractor to work with and receive support from an external organization with expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration with the goals of increasing diversity and quality of input to, efficiency in development of and effectiveness in monitoring of OPTN policy making process.

G.3. Describe what you would/vendors could include in their code of business ethics and conduct for the entity that holds this contract to ensure the highest standards of conduct and integrity are observed.

G.4. What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contract?

A better method of communication and engagement with stakeholders such as the AST is required. A call for public comment with short timelines and without context or commitment to

follow up or ongoing interaction suggests tokenism rather than a genuine effort to engage with stakeholders. We do not find this current method of obtaining input to be meaningful.

H. Stakeholder Engagement

H.1. Describe how you would/vendors could support the OPTN incorporating the NASEM report's recommendations on improving their stakeholder engagement efforts and activities, including whether and how to improve patient awareness of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions.

The society is willing to participate in genuine efforts to improve the system.

H.2. Describe how you would/vendors could support the OPTN in requiring OPTN members to adopt improved stakeholder engagement strategies that advance equity, access, and transparency.

H.3. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Inclusion of recipients and donors, as well as their families, in a transparent organ allocation process will reduce barriers and increase interest in organ donation.

It is important to note that successfully including patients/stakeholders in shared decision models requires accurate estimates of the key decision-making elements (i.e., if this organ isn't accepted, what is the likelihood that the patient survives until another, more acceptable organ becomes available and what is the likelihood that accepting this organ will meet shared graft/patient survival/quality of life goals). Unless reasonably accurate predictions of these two elements can be provided to stakeholders in a meaningful way it will be difficult to operationalize shared decision models effectively.

On behalf of the Society, thank you for this opportunity to share our thoughts. Please do not hesitate if we can be of further assistance or provide any clarification to our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "John Gill", written in a cursive style.

John Gill, MD, MS
President