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Restructuring the OPTN contract to achieve policy coherence and infrastructure excellence

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Abstract

The OPTN went up for competitive bid again this year, yet this contract has been held by only one entity since its inception. The OPTN's scope has grown steadily, and now embraces several disparate missions: to operate the computing and coordination infrastructure that maintains waiting lists and makes organ offers in priority order, to regulate transplant centers and OPOs, to follow and protect living donors, and to decide organ allocation policy in concert with the many voices of the transplant community. The contracting process and performance work statement continue to discourage both innovative approaches to the OPTN and competitive bids outside of UNOS, with evaluation criteria that either disqualify or strongly disadvantage new applicants. The performance work statement also emphasizes bureaucratic tasks while obligating the OPTN contractor to the specific committee structure that has impeded decision-making and tended to preserve the status quo in controversial matters. Finally, the UNOS computing infrastructure is antiquated and requires months to years to implement small changes. Restructuring the OPTN contract to separate the IT requirements from the policy/regulatory responsibilities might allow more nimble and effective specialty contractors to offer their capabilities in service of the national transplant enterprise.

Introduction

The Organ Procurement and Transplantation Network, created by the National Organ Transplant Act, establishes and implements allocation policies to distribute donor organs to individuals waiting for a transplant. The OPTN, in concert with the SRTR (1, 2), also oversees transplant programs and OPOs. Many stakeholders in transplantation feel that current allocation policies and oversight mechanisms have been too slow to change (3), that policy is implemented using an antiquated and error-prone IT infrastructure (4), and that innovations to the OPTN that have been widely discussed but not implemented would have benefited patients by increasing transplantation and improving equity in organ distribution (5). A few representative statements are: "By 2007 the overall framework for a new kidney

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allocation system was in place. So what took 7 more years?”(6) and “This unfair – and inefficient – status quo in transplantation has been acknowledged yet ignored for decades” (7).

The OPTN’s bylaws establish how its policies can be changed, but a new contractor would be free to propose different bylaws. The Final Rule requires that the OPTN solicit and consider public comment about proposed policies, and the policies must be approved by the Board; theoretically, these steps can be completed in less than one year. However, the OPTN bylaws permit literally endless discussion within a committee and the community after a policy problem has been identified (8). For example, deliberations about the new Kidney Allocation System lasted over a decade - and this was even after the kidney committee had taken the most contentious issue of geographic disparity off the table from the beginning (9). As another example, the Board of Directors declared that existing geographic disparity in allocation of organs was unacceptably high in 2012. In addressing the Board’s charge, the liver committee eventually requested the SRTR to test over fifty different systems, released two proposals for public comment, held two highly-attended public forums on the topic, and in the end rejected every one of the systems tested. Long years of clamorous discussion about reducing geographic disparity in liver allocation reached what seemed like a resolution in December 2017, when the Board (perhaps in response to the threat of a lawsuit) approved a diminished version of broader sharing. The approved allocation change promised substantially less impact on the problem than the Liver Committee’s first proposals, but was enacted as a compromise with those who wanted no changes at all to the geographic distribution of livers. With policy deliberations stretching over such long periods, the committee members who initiated a study rotated off and new members who lacked familiarity with the decisions already made often revisited and second-guessed those decisions, creating more delays and backtracking to options that were previously studied and dismissed.

In recent years, lawsuits alleging that organ allocation policies violated the Final Rule have more than once forced the OPTN to make emergency changes to organ allocation. The OPTN eliminated the DSA level of lung allocation over the 2017 Thanksgiving weekend to avert having to defend its allocation policy in court (10). The liver allocation compromise forged out of years of discussion will never be implemented, because OPTN is now legally obligated by a critical comment to change liver allocation again by December 2018, before the previously approved changes have even been programmed (11). These events highlight the need for policy changes to be made more rapidly and more effectively to implement defensible allocation rules. The OPTN has prioritized lengthy consensus-building and extensive study of policy changes while allowing new alternatives to be introduced ad infinitum. While consensus is valuable, OPTN must act more quickly and decisively to resolve inevitable conflicts of interests among transplant centers and other stakeholders. New thinking about the organizational structure of the OPTN, the roles of committees, the timeline of deliberations, and how to leverage different types of expertise could yield tangible benefits in transplantation.

OPTN Contract Process

The OPTN has been operated continuously by UNOS since 1986. The last time that the contract was offered competitively was 13 years ago, in 2005. By comparison, the SRTR contract is offered competitively every 5 years and has been held by three different organizations. In 2012, the government performed some market research for potential OPTN competitors, but did not offer the contract for bids. Instead, the government awarded UNOS a single-source contract for the OPTN. Some key steps in this and previous contracting processes are described in Table 1.

For the March 2018 request for proposals (RFP), the government provided a performance work statement, which in this case was a 71-page document detailing the contractor's obligations within the 224-page solicitation. Offerors were to respond with a technical proposal explaining how the following would be accomplished: hiring, project management, communication, monitoring OPTN members, a travel policy, avoiding conflicts of interest, providing direct electronic data transfer, and complying with the Final Rule. The offeror needed to name seven key personnel with their qualifications and time commitments, and describe the equipment and facilities that will be used to administer the OPTN.

According to the performance work statement, the functions of the OPTN contractor include "creating policies for the allocation of donated organs... consistent with the OPTN final rule." The offeror was asked to "describe the process that will be used to ensure that OPTN policies and Bylaws meet or conform to the requirements of NOTA and the OPTN Final Rule" (12).

The contract also required that the OPTN provide structured education to committee members about the legislative and regulatory requirements of NOTA and the OPTN final rule (12). These steps seem necessary but perhaps not sufficient to compel a fractious transplant community to bring allocation policy into compliance with the law. For example, in 1999, RAND concluded that "The continuing congressional efforts to delay implementation of the Final Rule and to redefine the contractor's role through a NOTA reauthorization bill underscore the unstable legal and regulatory environment in which any new OPTN contractor will have to function" and that members of the transplant community "lamented the descent into acrimony and interest politics" (13). In RAND's telling, "only a new task force that breaks out of the existing structure can bring together disparate medical, patient, family, financial, ethical, and political interests". Long years of intractable discrepancy between legal requirements and actual allocation policies should establish that a drastically different approach to policy making is called for.

Short timeline for RFP responses

Responding to this 224-page request for proposals would be a significant undertaking for any organization, yet it was issued with a deadline of only 31 days, essentially the legal minimum for these contracts. With substantial changes to the contract, the prior RFP from 13 years ago would not have been a reliable guide for preparing to respond to the current RFP. There were also quite significant changes between the December 1, 2017 request for

information (which included an early draft of the RFP) and the finalized RFP. Multiple respondents asked HRSA to extend the deadline for proposals to allow ninety days to prepare their bids. Any new organization preparing a bid would require more time than 31 days to prepare a response to this extensive RFP; only the organization that holds the current contract could feasibly apply for a contract of this magnitude in the allotted time. In 2005, the last time that the OPTN contract was offered competitively, prospective contractors were given 60 days to prepare their bids, yet the 2018 RFP required more work to prepare because HRSA requested more detailed business and technical information.

Organizational experience

The RFP specified that vendors would be evaluated on, “The Vendor (organization) experience as not-for-profit entity in the field of organ transplantation based on a minimum of three (3) years of corporate experience in managing projects of similar scope and complexity in the field of organ transplantation.” We struggle to identify other projects managed by not-for-profit corporations in the field of organ transplantation that are of similar scope and complexity to operating the OPTN. While it is reasonable for HRSA to require any OPTN contractor to have relevant experience in organ transplantation and allocation, this requirement set a bar that would be extremely difficult for anyone other than the current contractor to reach. However, dividing the functions of the OPTN into smaller, separate contracts (as delineated below) could allow more organizations to credibly bid.

Transition period and software transfer

Despite being asked at both the RFI and RFP stages, HRSA declined to state clearly whether an alternative contractor would gain access to key software that has been developed through the OPTN contract over many years to manage waiting lists, collect data, and implement organ allocation policies. Prospective contractors can only propose an appropriate transition plan after understanding what HRSA intends the software handoff to look like. The 2005 OPTN contract included language indicating that the government would require the current contractor to transfer software and data to any potential new contractor. A similar provision appears in the SRTR Work Statement. When the Minneapolis Medical Research Foundation (MMRF) took over the SRTR contract in 2010, the previous contractor, Arbor Research, transferred to MMRF the software it had developed under its contract, including the Simulated Allocation Models (SAMs) and associated input data sets, allocation rules, source code and documentation.

HRSA responded to a query about this: “there are no assets, property, or computer equipment that will be provided to the awardee. A bidder’s proposal must demonstrate that they have the staff, facilities, equipment, including software, to perform the required services that support the OPTN” (12). In this year’s request for proposals, HRSA initially specified a three month transition period. HRSA later changed that to a 6 month transition period, while stating that “the optional task for a transition-in period is not intended to provide a period of time for a contractor to develop an OPTN matching function”. Perhaps HRSA intended that any new contractor should pay UNOS for its software. We believe that designing better

software from scratch is the best option, but HRSA must allow a longer transition period if a completely new software system is to be realized.

UNOS estimated that it would take ten months or more to program the recently approved change to liver allocation. Considering ten months is UNOS' timeline to implement one change in one organ's allocation, it will require a great bolus of programming resources and intensive project management for a competitive bidder to re-engineer software for all of organ allocation and OPTN data collection. In withdrawing from the 1999 OPTN bidding process, from which they would have had slightly less than one year as a transition period, RAND Corporation stated, "We do not believe enough time will remain to smoothly develop and implement an entirely new information system" and that the short transition period increased their financial risk (13). HRSA and the transplant community quite reasonably expect a new contractor to be ready to go after a transition period, but HRSA should change the contract terms to allow a transition period adequate to the scope of work required to build new systems. One alternative would be for HRSA to fund one or more organizations to develop competitive IT systems in parallel with UNOS's efforts before awarding another contract.

Call to action: Suggestions for improvement

Recommended RFP changes to allow OPTN more operating freedom

Regardless of whether UNOS or another organization were the OPTN contractor, the RFP is so prescriptive in hewing to the existing structure that it might render infeasible the changes that could be beneficial to transplantation. Allowing or requiring the OPTN to recover its operating expenses from transplant recipients rather than from waiting list registrations might incentivize new approaches to increasing the number of organs available. The RFP also requires that OPTN maintain, in addition to its Board of Directors, a Nominating Committee, a Data Advisory Committee, a Finance Committee, a Policy Oversight Committee, a Network Operations Oversight Committee, a Membership and Professional Standards Committee, and other policy development governance groups. Eliminating the committee structure requirements in the OPTN contract would allow bidders to reposition decision-making authority, and perhaps to design an efficient process for policy revision that appropriately centers compliance with the law.

There is also a tension between keeping experts in the room long enough to complete work on a particular policy, and the broad participation that is repeatedly emphasized in the RFP. For example, the RFP requires OPTN to ensure "recruiting of new participants to bring new perspectives, and minimizing repeated appointments unless justified." A shorter timeline for policy decisions would mitigate the problem, but having to repeatedly orient new committee members to a policy development process that is already underway threatens timely progress. The contract should instead emphasize specific qualifications that people invested with decision-making authority should have: expertise in legal, scientific, clinical, ethical, or social aspects of transplantation, to ensure that decisions reached are defensible.

The contract gives HRSA an exacting role in monitoring the OPTN's administrative records, but leaves the difficulties of how to resolve long-standing conflicts between OPTN policies

and the requirements of the Final Rule to the contractor. As a small example, Bylaws changes that are likely necessary to improve the policymaking process must first be approved by HRSA's Contracting Officer Representative. The 18-page list of deliverables includes hundreds of reports to be filed, meetings to be conducted and documented, and forms that OPTN personnel must complete to the approval of the Contracting Officer Representative. We agree with the American Society of Transplant Surgeons, who recommended that "HRSA streamline and minimize the paperwork requirements imposed on the OPTN, and substitute tasks that focus more closely on substantive tasks that have the potential to further improve the expeditious and equitable distribution of organs" (14).

Recommended splitting of the OPTN scope

The RFP lists nine functions to be performed by the OPTN and ten objectives, as in Table 2. These functions can be roughly categorized as: data management and IT, assisting with realtime matching, policy development and communication, and oversight of transplant centers and OPOs. When it was established by the National Organ Transplantation Act, the tasks assigned to the OPTN were almost exclusively those data management and IT tasks of maintaining waitlists, running the match, disseminating data and information about transplantation, and assisting with realtime matching. In the decades since, fulfilling the OPTN's policy development role has become difficult, as controversy and gridlock threaten the OPTN's ability to conduct operations in accordance with law. As for oversight, the ASTS and others have recommended that HRSA reduce the oversight role of the OPTN and harmonize the duplicative regulation of transplant centers between CMS and OPTN.

The government should consider splitting the OPTN contract into at least two parts, one for building IT infrastructure and offering 24-hour support for organ placement, and another for policy development and governance functions. The OPTN contract now requires one organization to have expertise in these unrelated skills. This might be compared to asking Congress to write and manage software, or asking a hospital IT department to be responsible for creating all hospital policies. It would certainly be possible to separately contract some of these functions to different organizations. For example, the OPTN Board approved a new heart allocation policy on December 6, 2016, but software implementation has been delayed and is not scheduled to take effect until October 2018, over 18 months later. As another example, an error in UNOS IT programming caused the wrong KDPI to be reported for every single kidney offer in the United States for an entire month (4). Separating the tasks of programming match software and designing allocation policy might allow HRSA to choose a more nimble and efficient IT contractor. Further, the IT portion of the contract should be structured to allow for building completely new software, either by funding other organizations to build software before awarding the contract or by extending the transition period to allow sufficient time to develop new software.

The contract should obligate the IT provider to timelines for implementing changes to data collection, changes to compliance monitoring, and particularly changes to the organ offer rules and allocation algorithms. All of these functions of the OPTN are potentially life-altering for candidates awaiting a transplant. To take a few examples, the contractor could be required to continuously maintain the capability to revise or replace the allocation rules for

at least two organs at once, or for all organs, within a 6-month horizon, and to implement usability improvements and minor policy changes in DonorNet within 3 months.

Finally, one of the ten objectives listed is to conduct research on transplantation. We believe this should not be a core function of the OPTN given that (1) the broad academic community has proven itself capable of and motivated to conduct high quality research on transplantation; (2) the training required to conduct robust research is very different from that of any other OPTN functions; and (3) independent, outside academic review avoids the conflict of interest inherent when the OPTN evaluates its own policies and outcomes. In lieu of requiring the OPTN to do research, HRSA could fund other institutions to conduct what it considers essential research.

Conclusion

Viewed as an aspirational document and a vision for the OPTN, this RFP has much to recommend it. The RFP acknowledges the present shortcomings of the OPTN, listing “Obtain consistency of the OPTN and the Program with the National Organ Transplantation Act and the OPTN Final Rule” as the top objective. The RFP also properly prioritizes minimizing organ wastage and improving allocation policies to maximize the benefit of transplantation to those with end-stage organ failure (12). In an ideal world, the OPTN contractor would move quickly and decisively to achieve these objectives, and we expect UNOS will pursue these outcomes to the best of its capacity and authority. Ultimately, though, the best hope for excellence in administering the OPTN is through a competitive bidding process that encourages other organizations to propose innovative approaches and bring new competencies, and to relax some operating constraints on the OPTN. A transformative change could be within closer reach if the government awarded two or more separate contracts: one for the computer infrastructure that handles waiting lists and organ offers, and one for the policymaking and governance functions of the OPTN.

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Abbreviations:

ASTS	American Society of Transplant Surgeons
HRSA	Health Resources and Services Administration
OPO	organ procurement organization
OPTN	Organ Procurement and Transplantation Network
RFI	Request for Information
RFP	Request for Proposals

SRTR

Scientific Registry of Transplant Recipients

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Table 1.

Key dates and documents in current and past OPTN contracting processes

Process	Description	Release date	Deadline
Request for Proposals	The preceding solicitation of competitive bids for OPTN contract	Apr 15 2005	Jun 13 2005
Contract Awarded	UNOS wins OPTN contract	Sep 30 2005	Sep 30 2005
Sources Sought(15)	Government conducts market research to determine if capable sources exist	Jan 6 2012	Feb 17 2012
_____	<i>Government did not subsequently offer OPTN contract for bid in 2012</i>	_____	_____
Sources Sought(15)	Government conducts market research to determine if capable sources exist	Jan 27 2017	Feb 13 2017
Request for Information(16)	Government releases draft Performance Work Statement and requests feedback on it	Dec 11 2017	Dec 22 2017
Request for Proposals(12)	Government requests bids with 88 page solicitation and 71 page revised Performance Work Statement (71 pages) along with 56 page Quality Assurance Surveillance Plan	Mar 30 2018	Apr 30 2018* * revised to May 30 2018
New contract start date			Sep 30 2018

Table 2.

Functions of the OPTN(12)

	Function	Category
1	Maintaining a national list of individuals in need of one or more organ(s) for transplantation	Data management and IT
2	Matching organs to individuals on the waiting list	Data management and IT
3	Establishing and enforcing OPTN membership criteria for member entities and designated transplant program requirements	Oversight
4	Conducting reviews and evaluations of OPTN members and taking action consistent with the OPTN final rule and the OPTN Bylaws for OPTN member non-compliance, including referring matters to the Secretary.	Oversight
5	Creating policies for the allocation of donated organs and other policies authorized by the OPTN final rule consistent with the OPTN final rule	Policy development and communication
6	Maintaining a twenty-four-hour system to facilitate organ-recipient matching	Realtime matching assistance
7	Assisting organ procurement organizations (OPO) in the nationwide distribution of organs	Realtime matching assistance
8	Collecting, analyzing, and publishing organ donation and transplantation data	Data management and IT
9	Working actively to increase the supply and utilization of donated organs	Policy development and communication