OPTN Operations and Safety Committee
Allocation Out of Sequence Workgroup
Meeting Summary
March 19, 2025
Conference Call

Kim Koontz, MPH, Chair
Steven Potter, MD, Vice Chair

Introduction

The Operations and Safety Committee Allocation Out of Sequence Workgroup (the Workgroup) met via WebEx teleconference on 03/19/2025 to discuss the following agenda items:

1. Welcome
2. Review and Discussion
3. Closing Remarks/Adjourn

The following is a summary of the Workgroup's discussions.

1. Welcome

The Chair welcomed the Workgroup members. The Workgroup reviewed the objectives for the meeting.

2. Review and Discussion

The Workgroup reviewed the Allocation Out of Sequence (AOOS) directive from the Health Resources and Services Administration (HRSA) and the proposed project plan and timeline.

Presentation summary:

The Workgroup is addressing (A) 3-5 of the AOOS directive:

- A.3: Develop a proposed OPTN policy and associated definition to describe "batched organ offers"
- A.4: Develop a proposed OPTN policy and associated definition for the "offer" of an organ by an OPO to a transplant center
- A.5: Develop a proposed OPTN policy and associated definition to describe acceptable modalities and associated content of an organ offer made by an OPO to a transplant patient at a transplant center

Proposed project plan and timeline:

- Phase 1: A.3 and A.4 (defining "offer" and "batched organ offers")
- Phase 2: A.5 (define acceptable modalities and associated content of an organ offer)

Summary of discussion:

Decision #1: The Workgroup supported providing a response to HRSA that outlines recommendations for near-term and long-term approaches to addressing challenges in allocation out of sequence, which would focus on addressing root causes of AOOS prior to changing policy definitions.

The Workgroup discussed the meaning of "batch organ offer" and interpreted the directive as intending to prohibit open offers to a transplant program, rather than a group of organ offers. The Workgroup discussed whether the intent of defining "batch organ offer" is to facilitate expedited placement or to define a term for clarification.

A member described AOOS as a workaround for an allocation system that has not caught up with changing pressures on the system. Another member said they interpret "batch offer" as a proxy for offers to a center rather than offers to an individual. HRSA affirms in the directive that offers need to be made to an individual rather than to a center but that may impose challenges in the process. A member clarified that the Workgroup needs to define the ask to determine next steps.

Another member said there are many competing issues so the Workgroup needs to be clear and separate out the different issues. A member noted that the actual challenge is that the system is imperfect and as a result, AOOS is occurring to reduce non-use. The member recommended distinguishing between renal offers and non-renal offers since the drivers may be different. The member said perhaps there are a minority of cases in which AOOS should not be used, but there is a larger group of AOOS that reflects intent to place more medically complex organs with candidates other than those at the top of the list who have more access to offers from less medically complex organs. The member suggested distinguishing between those scenarios of AOOS for kidney as well as between kidney and other organs.

A member commented this effort feels like a band-aid and what needs to be considered is how the system can be designed to reduce AOOS. The member asked how the OPTN gets back to solving the problem and said the HRSA directive reflects an incomplete understanding of the system. The member recommended providing recommendations to HRSA for solutions that would more directly address the concerns raised.

Another member agreed that the Workgroup needs to acknowledge that the system is not working as intended and respond accordingly. The member said the OPTN does not need to develop more policy to explain how the process works. The member is concerned about how the work towards the AOOS directive has been divided since the expedited placement variance could inform solutions. The member voiced significant concerns of the directive being broken into three different section with different Committees working on this; there would be multiple Committees working on developing more policies, but is not this would not be solving the underlying problem. The member agreed with providing feedback to HRSA with a more comprehensive plan for addressing the problem.

A member recommended addressing the challenges via continuous distribution but noted that it is not going to be a quick solution. The member said that HRSA is ignoring the realities that brought the OPTN to this point. The member said there is a need to educate on why the system is functioning the way it is. Another member noted that European transplant systems do better jobs of allocating more medically complex organs due to different modalities depending on the donor (i.e., cold time).

A member acknowledged that the OPTN Kidney Transplantation Committee (Kidney Committee) is working on a kidney expedited placement policy but said that the OPTN Expeditious Task Force (Task Force) had already developed a proposed AOOS rescue pathway that HRSA put on pause. The member

recommended reinvigorating the Task Force and having the Task Force launch the plan-do-study-act (PDSA) pilot proposal that was in place. The Chair agreed that a lot of effort has been done by the Task Force and the response should include allowing that work to move forward.

The Chair said the requested timeline for the work is unworkable. A member asked if OPTN leadership could work with HRSA to develop a better working environment to accomplish this work collaboratively. Another member recommended that the plan should be to go back to the plan outlined by the Task Force. A member agreed that the focus should be on collaborating with HRSA to meet their goals on a more realistic timeline. There is an existing process that is evidence-based and has been vetted through public comment and that should move forward.

A Scientific Registry of Transplant Recipients (SRTR) representative noted they routinely use the term "batch offers" to refer to sending out a round of electronic offer notifications. The SRTR representative said that process seems to be completely legitimate and rational. The sequence number still defines who accepts the organ. The SRTR representative noted that "batch offers" may be used excessively but recommended that the Workgroup clarify how batch offers work in the current system to distinguish it from the offers that HRSA wants to prohibit. A member agreed that large batches of offers can be problematic from an efficiency standpoint but recommended confirming with HRSA what exact behavior needs to be prohibited.

Another member voiced concern that the Workgroup is being asked to respond but it is unclear what they are being asked to respond to. For example, recovery date and time has many different definitions in policy and the system, as does "batch offer." There are batched offers that are offered sequentially and there could be ten potential transplant recipients in a row on the match run listed at the same transplant center. Staff suggested thinking of the current electronic notification tool to avoid conflating it with "batch offers" is to think of it as a "sequential, simultaneous group of offers." The member said there is a narrative that exists but that may not be what the Workgroup should be responding to.

A member said that the problem that the Workgroup needs to address is patients being skipped. There are scenarios where a program has submitted a provisional yes and the OPO will place the kidney with a potential transplant recipient (PTR) lower on the list even though the higher transplant program would have accepted it for their candidate. Another member stated that members need to keep in mind how this problem arose in terms of OPOs developing aggressive center lists. When organs are shared more broadly, OPOs have developed those lists to place organs more efficiently. The Workgroup response should recommend solutions to address those problems. The member added that the problem that needs to be addressed is OPOs bypassing programs of their own volition.

Another member said that the Workgroup understands the issues and should work together as a community to create guardrails that will engender trust in the process. A member agreed with this and added that systems are not fixed by developing policy; the system itself needs to be fixed. The member stated that the community spends multiple years collecting data to inform solutions; the system is moving faster than the data can be collected. Another member agree with this and stated that additional data is not needed. A member added that there is a lot of work that are currently being done and completing continuous distribution would help address these concerns, but the scope of that work is large and will take time.

An SRTR representative suggested that AOOS in of itself is not always a problem but the problem seems to be that the frequency of AOOS is too great. The SRTR representative recommended that the workgroup delineate when AOOS is acceptable and when it is not as currently the process is too frequent and too variable, depending on individual OPO processes.

A member said that a lot of OPOs don't use an "aggressive center list". The member suggested that it would be helpful to understand variability in OPO practice and propose some solutions that reduce the need to go to a "fail-safe" option. The member asked how the Workgroup can propose solutions to make the process more efficient. The member said it was clear that HRSA did not understand how open offers work but what was alarming in the letter was the idea that transplant programs can accept organs and come up with a justification for putting the organ in another patient, and it is important to clarify that there is not a desire to place an organ with a particular program but rather to ensure the organ is placed.

A member shared a picture of kidneys that were hard to place and acknowledged the challenge for OPOs in finding a transplant program that would accept the kidneys for their candidates. The member said the details of the definitions is not the issue; it's that when work arounds become the norm, then there is something wrong with the process. The member continued by stating that the issue is inflamed by mentioned of surgeons receiving calls to their cell phones about offers that raise questions and should be addressed. There is also a need to address bypassing programs haphazardly. The member suggested there needs to be guardrails around bypassing programs.

A member said that the Centers for Medicare and Medicaid's (CMS) formal response to OPOs, this question was raised and CMS specifically stated, "…therefore, we do not believe the constraints of the allocation system justified not successfully placing a transplantable organ. We believe that this Final Rule will allow OPOs the opportunity to improve the placement of organs and drive the transplant community to adopt the technologies necessary to optimize placement". The member stated that this statement was specifically commenting on the section in the OPTN Final Rule around wastage. CMS as the regulatory oversight entity for OPOs said that OPOs are accountable for placing these organs. CMS did not say that OPOs were hamstrung by the organ wastage provision of the Final Rule. Another member said this is important to include in the OPTN response because CMS and HRSA need to coordinate.

Contractor staff noted that the request at this stage is to provide a response to HRSA that outlines the project plan. The response will be provided to the OPTN President and HRSA for feedback. The Workgroup can recommend highlighting issues that need to be considered before moving forward with specific solutions. This response could include recommendations for taking a different approach than what is outlined in the directive. A member said including education in the letter is important since members of the Workgroup are not convinced that HRSA understands what members are dealing with in practice and the problems they are trying to address, so that is necessary to engender more collaboration.

Another member suggested proposing steps in a different sequence which could include system, process, match, and waiting list solutions. The Workgroup could outline a phased approach for tackling those suggestions instead of a phased approach for defining an offer. A member said that the phased approach should focus on education and collaborating.

A member said that in providing feedback and education back to HRSA, the Workgroup needs to be very careful about the language. The member added that the Workgroup should not presume HRSA is coming from a place of naivete whether or not there is agreement. Another member replied that the response should be that HRSA wants fast and the Workgroup wants a solution that is good; good solutions cannot be achieved quickly. Members do not want to go out of sequence but it is a fear-driven approach to preventing organ loss. The member acknowledged that HRSA is also feeling a lot of pressure and reiterated that the focus should be on collaboration.

Another member stated that the Workgroup is aware of failures in the system so the Workgroup should focus on addressing those failures and acknowledge that in the response to HRSA. A member suggested establishing some minimum ground rules as there are some outliers in terms of frequency of AOOS. That would be a band-aid solution, but establishing a minimum set of expectations may help to alleviate the issues while working towards longer term solutions.

Another member agreed and recommended responding with a "yes, and" approach which outlines what the Workgroup plans to achieve in the near-term and what will be addressed on a longer timeframe. The member said this is the Workgroup's opportunity to influence change and outline recommendations for improving the system. The member recommended that the Workgroup move from reacting to the directive to responding with how they'd like to proceed.

There were no additional comments. The meeting was adjourned.

Next Steps

The Workgroup will reconvene on March 21st to continue the discussion. In the interim, the Workgroup will share an update with the OPTN President on the approach being considered by the Workgroup for any preliminary feedback.

Upcoming Meeting

- Friday, March 21, 2025 (Teleconference)

Attendance

- **Workgroup Members**
  - Kim Koontz (Chair)
  - Steve Potter (Vice Chair)
  - Anja DiCesaro
  - Anne Krueger
  - Chris Curran
  - Collen Jay
  - David Marshman
  - Amanda Bailey
  - Jamie Bucio
  - Jason Smith
  - Jim Kim
  - Justin Wilkerson
  - Kaitlyn Fitzgerald
  - Karl Neumann
  - Meelie DebRoy
  - Robert Johnson
  - Sarah Koohmaraie
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - Nick Wood
- **UNOS Staff**
  - Joann White
  - Ben Woolford
  - Betsy Gans
  - Chelsea Hawkins
  - Kaitlin Swanner
  - Laura Schmitt
  - Lloyd Board
  - Matt Cafarella
  - Niyati Upadhyay
  - Rebecca Fitz Marino
  - Rebecca Murdock