

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Redefining Provisional Yes and the Approach to Organ Offer and Acceptance

The American Society of Transplant Surgeons (ASTS) is generally in favor of reforming the approach to organ offer and acceptance to improve efficiency of placement. Redefining the Provisional Yes is certainly a part of it, but fundamental revisions beyond this are needed to modify/improve processes within the organ offer/placement pathway to optimize this ecosystem. This includes but is not limited to, incentives for programs and OPOs to promote efficiency, establishing standard criteria for conduct of organ procurements, establishing criteria for procurement surgeons, and optimizing safety/efficiency of organ transport.

The three-tiered system proposed adds granularity to understand where in the placement process the centers are, in addition to increasing the accountability of responding programs somewhat. The drawbacks include potential micromanagement of the placement pathway when practices vary around the country, leading to programs feeling locked into pathways that don't fit into their optimal workflow.

Tiered Framework

What should happen if the first program refuses the organ offer (in Tier I)?

In the first version of this endeavor, it would be best not to penalize programs that turn down after Tier 1. Rather, it would be considered valuable to assess the success of this new system and should be used for evaluating at periodic intervals.

• What information should OPOs be required to complete for a Tier III offer evaluation?

OPOs should have the donor record completed and ready as with the current system prior to sending out offers.

Are there tools that should be considered that could help facilitate this three-tiered model?

Transparency would be critical for success of any model. Therefore, the proposal to not white out OPO information is welcomed. In addition, there may not be a need to white out center information as well, as this will likely not impact confidentiality.

Associated Requirements within Tiers

Are the requirements within each tier reasonable?

Generally, yes, with the caveat that there is a risk of overprescribing the requirements for each tier. For example, it may not be reasonable for the tiers to determine when candidate availability should be determined. The proposal suggests Tier 1, but many programs do that much earlier in the process.

• Should OPOs limit offers based on tiers? Should this be based on the number of organ offer responses that are confirmed?

Yes, this will be a key element to improving efficiency and getting center buy-in. The initial number of offers should be based on the number within which the organ has a reasonable chance of getting placed. This may need a sophisticated algorithm which should be developed based on donor factors, organ characteristics, and other variables such as geography, time to procurement, etc. The number of offers should come down as the tiers move up to 1.

Should there be expectations outlined that are specific to offers sent pre- and post-recovery?

Rather than having a dichotomous plan for pre- vs. post-procurement, a continuous variable based on proximity to clamp time (on either side pre- or post-), in combination with other factors could be used for decisions on number of offers (as stated in the response to the previous question)

Tier Thresholds (number of offers sent)

• Do you agree with the recommended thresholds for each tier?

Generally, yes. Each tier should incrementally increase the accountability for provisionally accepting the organ.

• What threshold should be considered for Tier III for when should a program receive the initial notification?

If the program has expressed an interest in receiving such organ offers as the one being offered (during the listing process), they should not be bypassed.

Time Limit on Offers

Do you agree with the recommendations on time limits on offers for Tier I and Tier II?

Yes.

• Should there be different considerations for offers sent pre- and post-recovery? If so, what should those considerations be?

Yes.

Should there be a time limit for Tier III to respond to a notification on an organ offer?

Yes, and it should be consistent with current standards for the Provisional Yes.

ASTS Position: Neutral/Abstain