Concept Paper

OPTN/UNOS Organ Procurement Organization Committee

Expedited Organ Placement Concept Paper

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Executive Summary

Expedited organ placement has been an important part of organ allocation for many years. Organ procurement organizations (OPOs) utilize this method to quickly place organs that are at risk of discard. OPTN/UNOS policy does not currently address expedited placement except for *Policy 11.6: Facilitated Pancreas Allocation*. Consequently, during recent discussions about broader sharing and system optimization, the community has expressed a want to better understand expedited placement, understand its impact on transplant candidates, and to maximize utilization of transplantable organs. The OPO Committee ("the Committee") is seeking feedback from the donation and transplant community. The Committee intends to use this feedback in the development of policy language intended to address the following problems:

1. Lack of transparency with the current system
2. Lack of guidance for OPOs and transplant hospitals
3. Lack of consistent practice across the country
4. Inconsistent access to organs for candidates in need of transplant

Due to the complexity of this issue, the Committee made the decision to focus on the liver allocation process during the initial phase of this project. The intent is to develop a framework for expedited placement, initially focusing on liver placement, that can eventually be applied to the other organ systems.

The Committee determined that any expedited placement system is likely to have three components:

1. A trigger – the determination to perform expedited placement
2. A mechanism – the way expedited placement gets initiated in the match system
3. A qualification – the determination of how transplant hospitals qualify to receive expedited offers on behalf of their patients

The Committee determined that separate triggers are needed to address the different scenarios that might lead OPOs to initiate expedited placement:

1. Prior to donor recovery procedure (pre-operating room or "pre-O.R.")
2. In the operating room

The Committee is aware that certain transplant hospitals are more likely to accept expedited placement offers than others. Therefore, the Committee would like to address how transplant hospitals qualify to receive expedited offers.

One additional concept being considered is a way to "expedite" the allocation of most or all organs by incorporating factors targeting organ utilization into the allocation algorithm. For example, the probability of discard and/or the probability of a candidate's or hospital's acceptance. This concept is more of a long-term goal due to its complexity and potential impact on organ allocation.

The Committee seeks public comment on these concepts and will use the information as it develops future policy proposals. The Committee is concerned that proposing a system that is too cumbersome will have a negative impact on the expedited placement process and could result in a loss of organs for transplant. The Committee plans to circulate an initial policy proposal during the fall 2018 public comment cycle.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

Yes, the Committee is requesting feedback on the following questions:

1) Should an allocation system include an expedited placement trigger based on defined donor characteristics that would allow an OPO to expedite the placement of an organ?
2) Should an allocation system include an expedited placement trigger based on an event like an organ declined in the OR that would allow an OPO to expedite the placement of an organ?
3) Should the allocation system allow an OPO to move to an expedited list after a well-defined point in the allocation process (e.g., after offers to x candidates, after offers to x hospitals, within x hours of the scheduled OR time)?
4) Once an expedited placement trigger has been met, should the OPO use their own discretion to get the organ placed for transplantation?
5) Once the expedited placement trigger has been met, should the list of potential candidates be limited to those at transplant hospitals with a recent history of transplanting organs from similar donors?
6) Should transplant hospitals be allowed to choose whether or not they want to have their candidates on an expedited list?
7) Should the allocation system give higher priority to candidates more likely to accept an organ that has a higher likelihood of discard based on statistical models?
8) Should DonorNet® set a transplant hospital's acceptance criteria based on the hospital's past acceptance practices?

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Sponsoring Committee: Organ Procurement Organization

Public Comment Period: January 22 – March 23, 2018

What problem will this concept solve?

The number of livers placed using expedited placement remains low. Overall, the number of expedited placement cases by OPOs make up less than 2% of all transplants each year. According to OPTN data[1], over a two year period between January 1, 2015 and December 31, 2016, there were 476 liver transplants documented as using expedited placement.[2] The OPTN monitors every allocation and "out of sequence" allocations are reviewed by the Membership and Professional Standards Committee (MPSC). Below is a summary of the MPSC data reviewed by the Expedited Placement Work Group (hereafter referred to as the "work group"):

- Each year, approximately 70% of OPOs had at least one expedited placement case reviewed by the MPSC
- Most OPOs have between 1 and 10 cases
- A small number of OPOs had approximately 40 expedited placement cases reviewed per year
- 60% of liver expedited placements reviewed were associated with intra-operative turndowns
- 20% of expedited liver offers were associated with pre-cross clamp refusals for organ quality
- Four liver transplant programs received almost 50% of the expedited liver offers
- Approximately 30% of the expedited livers are reported to have >20% macro vesicular fat
- The vast majority of expedited placements reviewed by the MPSC were determined to be an appropriate use of expedited placement

The issue of expedited placement has been addressed in several publications and editorials. In a 2012 editorial in the *American Journal of Transplantation*, Washburn et al[3] raised the same questions about utilization, equity, and transparency being discussed by the work group. Kinkhabwala et al[4], recommended the development of policies governing expedited placement "in order to improve access to available organs."

It is clear that the process for expedited placement lacks transparency and consistency across the country. Current OPTN policy addresses the facilitated placement of pancreata, but does not address the expedited placement of other organs when OPOs need to place organs due to time constraints (donor family, donor issues, late turndowns, hemodynamic challenges, etc.) or when a particular organ is "hard to place." This absence of policy language creates the following problems:

1. Lack of transparency with the current system
2. Lack of guidance for OPOs and transplant hospitals
3. Lack of consistent practice across the country
4. Inconsistent access to organs for candidates in need of transplant

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[1] Descriptive data request prepared for Aug. 28, 2017 work group conference call
[2] For this analysis, expedited placement is defined as any match run that had at least one candidate prior to the final acceptor that was bypassed for an "expedited" reason.
[3] Washurn K, Olthoff K. Truth and Consequences: The Challenge of Greater Transparency in Liver Distribution and Utilization. Am J Transplantation 2012; 12: 808-809.
[4] Kinkhabwala M, Lindower J, Reinus JF, Principe AL, Gaglio PJ. Expedited Liver Allocations in the United States: A Critical Analysis. Liver Transplantation 2013; 19: 1159-1165.

The goal of this work is to develop a system that addresses these problems without compromising the ability to get organs transplanted.

What are the concepts being considered?

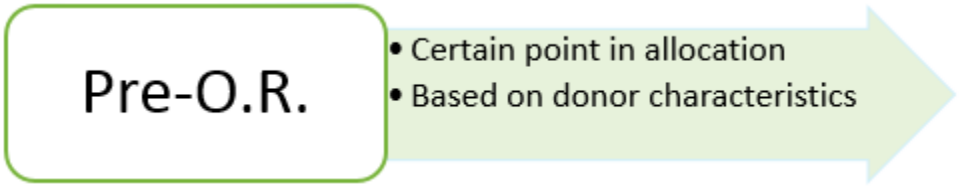
The Committee is proposing several concepts to address the expedited placement of livers:

- Trigger concepts
- Mechanism concepts, and
- Qualification concepts.

Trigger Concepts

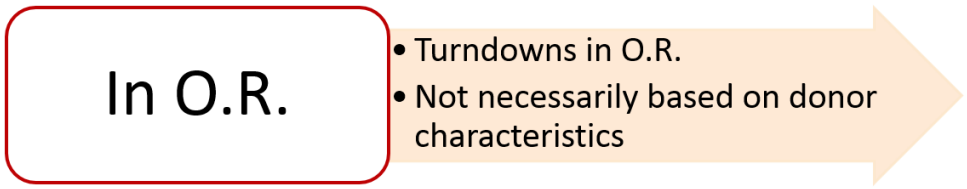
First, the Committee is proposing two triggers for expedited placement based on different time points.

Trigger 1 – Pre O.R. (operating room)



This trigger would be based on donor characteristics that make the organs "hard to place," or at "high risk for discard." For example, the donor characteristics developed by the Liver and Intestinal Organ Transplantation Committee ("Liver Committee") as shown in **Tables 1 and 2**. At a certain point during the allocation process the placement could become more expedited. This could be automatic at the start of the allocation process or at a certain point in allocation.

Trigger 2 – In O.R. (operating room)



This trigger addresses the late turndowns which require OPOs to move quickly to place organs to ensure the liver is utilized. This is more focused on moving quickly to avoid discards and is not necessarily based on donor characteristics.

Specific questions for feedback:

1) Should an allocation system include an expedited placement trigger based on defined donor characteristics that would allow an OPO to expedite the placement of an organ?
2) Should an allocation system include an expedited placement trigger based on an event like an organ declined in the OR that would allow an OPO to expedite the placement of an organ?
3) Should the allocation system allow an OPO to move to an expedited list after a well-defined point in the allocation process (e.g., after offers to x candidates, after offers to x hospitals, within x hours of the scheduled OR time)?

Mechanism Concepts

The mechanism for expedited placement will be the system changes necessary to operationalize the process. This will include a way for OPOs to electronically initiate expedited placement using one of the

triggers as well as the identification of transplant hospitals that will receive the offers. Since these are only concepts, additional information about the mechanism will be provided as the Committee develops a future proposal.

Specific questions for feedback:

4) Once an expedited placement trigger has been met, should the OPO use their own discretion to get the organ placed for transplantion?
5) Once the expedited placement trigger has been met, should the list of potential candidates be limited to those at transplant hospitals with a recent history of transplanting organs from similar donors?

Qualification Concepts

The work group has discussed how transplant hospitals qualify for expedited offers.

- For ***Trigger 1***, which focuses on donor characteristics, transplant hospitals could qualify for the expedited list based on acceptance history for donors with similar characteristics. The work group also discussed that transplant hospitals not currently on the list could demonstrate acceptance of such organs in order to qualify for the expedited list.

- For ***Trigger 2***, the identification of transplant hospitals for this expedited list is more difficult because it is not necessarily based on donor characteristics. Additionally, if the list is too long it could actually lead to more discarded organs. The Committee is seeking feedback on this issue.

Specific question for feedback:

6) Should transplant hospitals be allowed to choose whether or not they want to have their candidates on an expedited list?

How were these concepts developed?

The work group members agreed that one of the components of expedited placement is the trigger. As mentioned above, the work group members agreed there should be different pathways for "pre-O.R.' and "in-O.R." expedited placement. For pre-O.R. expedited placement, there was a recommendation to require local and regional allocation before initiating expedited placement. This is similar to a 2013 recommendation by Lai et al[5] in which livers, once "refused at both local and region levels", are offered simultaneously to all transplant hospitals with a provisional yes acceptance and allocated to the candidate ranked highest on the match run.

Organ turndowns in the donor O.R. would be the second trigger for expedited placement. This trigger is more easily defined because the donor is in the O.R. and would not necessarily be based on donor characteristics. The work group discussed the possibility of including additional timeframes such as when the O.R. time is set or within 3 hours of O.R. There were concerns about these due to the various factors that might affect O.R. time.

Identifying the transplant hospitals that would show up on an expedited list might be dependent on which trigger is used. For the pre-O.R. trigger, the criteria for transplant hospitals could be based on acceptance history. For the in-O.R. trigger, the work group is trying to determine if national allocation is feasible due to the need to place the organs more quickly.

The Committee recognizes the need to have a mechanism for transplant hospitals that fall outside of the criteria to be added to the expedited list. For example, this could be accomplished by a demonstrated

[5] Lai JC, Feng S, Vittinghoff E, Roberts JP. Offer Patterns of Nationally Placed Livers by Donation Service Area. Liver Transplantation 2013; 19: 404-410.

change in acceptance behavior. There was discussion about how some transplant hospitals occasionally utilize marginal organs while others use them on a regular basis. Work group members agreed that the community needs to decide if it is worth slowing down allocation in order to include certain transplant hospitals with a low likelihood of accepting the liver. For example, if a transplant hospital only accepts one liver per year from a donor over 70 years of age, should they be included on the expedited list? If the goal is to efficiently allocate at risk livers to avoid discards, there needs to be a balance that allows allocation to hospitals that will use them without creating a disadvantage for other hospitals.

Review of Data

The work group initially requested data to analyze how many transplant hospitals would qualify for expedited placement based on the donor profiles developed by the Liver Committee. **Table 1** shows the number of transplant hospitals that performed at least one liver transplant using the Liver Committee profiles. Note that profiles 1-5 and 6-11 are not mutually exclusive. As you can see, there were a significant number of transplant hospitals (131 or 93% of liver transplant hospitals) that met at least one of donor profiles 1-5. Additionally, 118 transplant hospitals (84% of liver transplant hospitals) met at least one of the donor profiles 6-11.

Table 1: Number of Transplant Centers Performing at Least One Liver Transplant by Profile - 2015-2016

Profile	N	
1: Biopsy done & HCV+	90	131 centers met at least one profile (1-5)
2: No biopsy & Donor age 71+	38	
3: No biopsy, Donor Age $<$ 71 & DCD	83	
4: No biopsy, Donor Age $<$ 71, DBD & HCV+	65	
5: No biopsy, Donor Age $<$ 71, DBD, HCV- & Blood infection	124	
6: HCV+	98	118 centers met at least one profile (6-11)
7: HCV- & Donor age $>$ 75	46	
8: HCV-, Donor age $\leq$ 75 & BMI $>$ 42.1	88	
9: HCV-, Donor age $\leq$ 75, BMI $\leq$ 42.1 & DCD	87	
10: HCV-, Donor age $\leq$ 75, BMI $\leq$ 42.1, DBD & HBV+	97	
11: Donor age 59-74, BMI $\leq$ 42.1, DBD & HBV-	108	

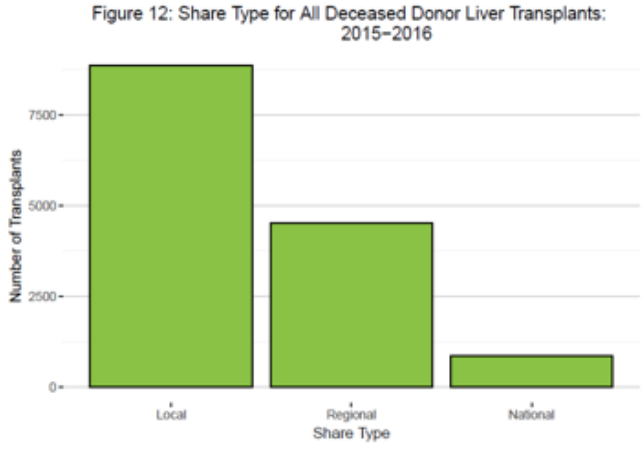
In a separate analysis, the work group reviewed expedited liver transplants (defined as a transplant that had at least one potential recipient bypassed with an expedited bypass documented as the reason for bypass). The group looked at how many expedited liver donor transplants were performed that fit each of the donor profiles: 2015-2016. **Table 2** shows that for profiles 1-6, there were 86 transplants and for profiles 7-11, there were 209 transplants.

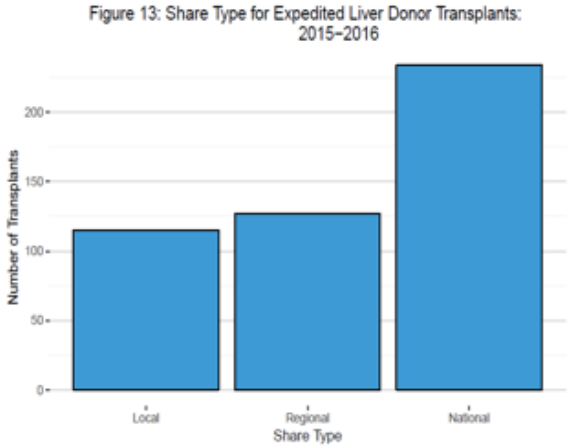
Table 2: Number of Expedited Liver Donors Transplants by Profile: 2015-2016

Profile	N	
1: Biopsy done & HCV+	38	
2: No biopsy & Donor age 71+	4	
3: No biopsy, Donor Age < 71 & DCD	30	86
4: No biopsy, Donor Age < 71, DBD & HCV+	2	
5: No biopsy, Donor Age < 71, DBD, HCV- & Blood infection	12	
6: HCV+	40	
7: HCV- & Donor age > 75	14	
8: HCV-, Donor age ≤ 75 & BMI > 42.1	40	
9: HCV-, Donor age ≤ 75, BMI ≤ 42.1 & DCD	40	209
10: HCV-, Donor age ≤ 75, BMI ≤ 42.1, DBD & HBV+	18	
11: Donor age 59-74, BMI ≤ 42.1, DBD & HBV-	57	
12: No Profile	257	

The work group also analyzed the types of liver transplants by share type as shown in **Table 3**. There were a higher percentage of national shares for expedited placement (49.2%) compared to all deceased donor liver transplants (6%).

Table 3: Liver Transplants by Share Type (Local, Regional, National)





While the Committee reviewed data on which livers were allocated using expedited placement, there is limited information about when OPOs made the decision to go to expedited placement. This is because potential transplant recipient (PTR) information is not entered in real time; instead, *Policy 18: Data Submission Requirements* states that information must be submitted within "30 days after the match run date by the OPO or OPTN Contractor." The work group members agreed that the timing of expedited placement is key to the discussion. The work group acknowledged that donor characteristics might not accurately predict when a liver might get expedited. There are behavioral and "events in the OR" that are difficult to identify and analyze. The work group agreed that the donor characteristics in combination with another event could serve as a trigger for expedited placement.

Additional concept being considered

Currently, the OPTN's organ allocation algorithms take into account factors related to equity (e.g., CPRA, waiting time, pediatric status) and utility (e.g., waiting list mortality, post-transplant survival, and/or net-benefit), but they do not explicitly include factors targeting organ utilization. A concept aimed at addressing this gap would be to "expedite" the allocation of most or all organs by incorporating into the allocation algorithm the probability of discard and/or the probability of a candidate's or hospital's acceptance. Statistical models would be used to predict likelihood of an organ being refused or discarded. These models could be incorporated into the allocation algorithm in this way, for example:

- If the discard probability exceeded a threshold (e.g., 50%), candidates with higher probability of acceptance would receive increased allocation points or priority to move them higher on the list. If the discard probability exceeded a higher threshold (e.g., 75%), candidates with higher probability of acceptance would receive a substantial number of allocation points to move them higher on the list.
- Alternatively, instead of using a discard probability threshold, a continuous approach could be used in which the degree to which the candidate's offer acceptance probability affected the candidate's prioritization on the waiting list increases gradually as the discard probability increases.

This approach would allow candidates (and hospitals, if hospital effects were included in modeling) more likely to accept particular offers the opportunity to receive these offers earlier in the organ placement process, reducing the chances of discard due to accumulated refusals and cold ischemic time.

The idea of having the system "force" hospital screening criteria has also been discussed as a way of shortening the number of offers needed to place an organ. The system could use a hospital's past acceptance rates behaviors as the "default criteria" to enforce more realistic screening criteria that would be applied globally to the candidates on their list. This forced screening could be based on the current, one-factor-at-a-time offer acceptance criteria (e.g., age<60) or a new, multi-factor offer filtering paradigm that is currently being discussed. The system could also include a way for transplant hospitals to modify their acceptance criteria at regular intervals (e.g. every 2 months) in response to the default criteria.

Specific questions for feedback:

7) Should the allocation system give higher priority to candidates more likely to accept an organ that has a higher likelihood of discard based on statistical models?
8) Should DonorNet® set a transplant hospital's acceptance criteria based on the hospital's past acceptance practices?

Conclusion

The Committee is seeking input from the community on the concepts identified in this paper. The goal of this concept paper is to solicit feedback from the community to assist the Committee as it develops a proposed expedited placement system that creates a balance between transparency, efficiency, and equity.

How does this concept support the OPTN Strategic Plan?

1. *Increase the number of transplants:* This project has the potential to increase the number of transplants by standardizing expedited placement practices across OPOs. There is also the potential to reduce the number of transplants if the final policy language is cumbersome and creates barriers for OPOs during expedited placement.

2. *Improve equity in access to transplants:* This project could increase access to transplants by requiring OPOs to offer organs to transplant hospitals that were previously bypassed during expedited placement.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This project will increase the efficient management of the OPTN by reducing the number of cases being reviewed by the MPSC.