Proposal at a glance

Public Comment Proposal: Expedited Placement of Livers
Sponsoring Committee: OPTN Organ Procurement Organization Committee

You may be interested in this proposal if

- You work for an OPO
- You work for a transplant hospital
- You are currently on the liver waitlist

Here's what we propose and why

Sometimes when OPOs are already in the operating room with the donor, they will hear from transplant centers that they no longer want to receive the liver they accepted for their candidate. When this happens, the OPO has to act quickly to try and place the organ elsewhere. Because we have no current policy in place that specifically addresses this situation, we are proposing an idea that would make it easier for OPOs to place these types of organs quickly and reduce the chance that they are discarded without being transplanted. If transplant centers are interested in receiving an offer of this type, this proposed policy would require them to report specific information in advance. It would also give OPOs specific guidance on how to conduct these cases, including the amount of time the transplant center has to respond, so that all expedited offers are handled consistently and uniformly across the country.

Why this may matter to you

This policy change would give OPOs early access to a list of transplant centers who are interested in accepting this type of offer for their candidate. This means OPOs could begin making back up plans before they ever enter the operating room.

Transplant hospitals would have the opportunity to indicate their willingness to accept an expedited liver offer, but in order to participate they would be required to enter specific acceptance criteria advance.

Tell us what you think about

- Would this proposal help OPOs more quickly place livers that are turned down in the donor operating room?
- During a previous public comment, many people were concerned that initiating expedited placement in the donor Operating Room was too late in the process. Does allowing OPOs to identify expedited liver candidates on the original liver match run address that concern?

OPTN

Public Comment Proposal

Expedited Placement of Livers

OPTN Organ Procurement Organization Committee

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Contents

Expedited Placement of Livers

Affected Policies:	*Policies 1.2: Definitions; 5.3.D: Liver Acceptance Criteria; 5.6.B: Time Limit for Review and Acceptance of Organ Offers; 9.10.A: Expedited Liver Placement Acceptance Criteria; and 9.10.B: Expedited Liver Offers*
Sponsoring Committee:	*Organ Procurement Organization*
Public Comment Period:	*August 2, 2019 – October 2, 2019*

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 not being used for transplant. OPTN policy does not currently address expedited placement with the exception of *Policy 11.6: Facilitated Pancreas Allocation*. Consequently, during recent discussions regarding broader organ distribution and system optimization, the community expressed an interest in better understanding expedited placement and its role in addressing the issue of late liver turndowns. The goal of this proposal is to address the following issues related to expedited placement:

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

The OPO Committee (hereinafter referred to as "the Committee") submitted this proposal for public comment during the January-March 2019 cycle. The main concerns raised during public comment were that initiating expedited placement from the donor operating room (OR) is too late in the process and 20 minutes for transplant hospitals to respond to expedited liver offers is not enough time. In response to public comment, the Committee made the decision to revise the proposal and clarify the process by which livers will be allocated using expedited placement. This proposal still requires transplant hospitals to enter candidate-level acceptance criteria to opt in to receive expedited livers and allow additional screening on the liver match run for expedited offers. OPOs will have the ability to see expedited candidates on the original liver match run which will allow for advance communication and planning in the event expedited placement is necessary. However, expedited liver offers can only be sent by the host OPO once the conditions outlined in the proposal have been met. Finally, the previously proposed time limit of 20 minutes for transplant hospitals to respond to these offers has been changed to 30 minutes.

What problems will this proposal address?

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[1] raised the same questions about utilization, equity, and transparency being addressed in this proposal. Kinkhabwala et al[2] recommended the development of policies governing expedited placement "in order to improve access to available organs."

Current OPTN policy addresses the facilitated placement of pancreata, but does not address the placement of other organs when OPOs need to place organs in an expedited fashion. The absence of policy language creates the following problems:

1. Lack of transparency about how organs are placed using expedited placement
2. Lack of guidance for OPOs and transplant hospitals when there is a need to utilize expedited placement
3. Lack of consistent practice across the country which could reduce access to organs

The goal of this proposal is to create a transparent system that addresses the above problems without compromising the ability to place and transplant livers. The absence of policies require OPOs to justify any deviation from the match run when they use expedited placement. Additionally, OPOs might be reluctant to make additional liver placement efforts due to concerns about Membership and Professional Standards Committee (MPSC) review.

While the OPTN does not collect information on late turndowns in the donor operating room, there was anecdotal evidence presented during Expedited Placement Workgroup discussions and early reports from a study being conducted by the Association of Organ Procurement Organizations (AOPO) that suggests the number of late turndowns throughout the U.S. could be quite significant. During its April 16, 2019 meeting[3], the Committee was provided with an update on the study being conducted by AOPO. While this is an ongoing study and no formal results have been published, the data illustrate that late turndowns of livers is an issue. Data collected within the two years of the study from 38 of 58 OPOs showed 880 total declines in the OR. Among the 880 total declines, 243 cases were not recovered. There were 619 (70%) cases that were recovered with the intent to transplant, but there were only 323 (52%) which were actually transplanted. Among those organs that were transplanted, 165 (51%) of the cases were back up placements and 137 (42%) cases were expedited placements.

Additionally, as part of the Workgroup discussions, data showed that for expedited liver offers reviewed by the MPSC (476 over a two year period), 60% were associated with intra-operative turndowns.[4]

Background

Following the approval of this project, the Committee formed a joint Workgroup (hereafter referred to as the "Workgroup") with representation from the following committees:

- Liver and Intestinal Organ Transplantation Committee
- Membership and Professional Standards Committee

[1] Washburn K, Olthoff K. Truth and Consequences: The Challenge of Greater Transparency in Liver Distribution and Utilization. Am J Transplantation 2012; 12: 808-809.
[2] 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.
[3] https://optn.transplant.hrsa.gov/media/2961/20190416_opo_-minutes.pdf
[4] 1 Descriptive data request prepared for Aug. 28, 2017 Workgroup conference call

- Transplant Coordinators Committee

Overall, the number of expedited placement cases across all organ types by OPOs make up less than 2% of all transplants each year. According to OPTN data,[5] over a two year period between January 1, 2015 and December 31, 2016, there were 476 liver transplants documented as using expedited placement.[6] A more recent cohort showed that between January 1, 2016 and December 31, 2018, there were 523 liver transplants documented as using expedited placement. The OPTN monitors every allocation and "out of sequence" allocations are reviewed by the Membership and Professional Standards Committee (MPSC).

The Workgroup reviewed the following information provided by the MPSC:

- Each year, approximately 70% of OPOs had at least one expedited placement case reviewed by the MPSC
- Most OPOs had 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 greater than 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 Workgroup members recommended that the components of expedited placement should include specific acceptance criteria provided by the transplant hospitals, criteria for allowing OPOs to initiate expedited placement, and a mechanism for efficiently sending and receiving expedited liver offers.

Proposed Solutions

Requirements for Transplant Hospitals

The Committee distributed a concept paper[7] for public comment in early 2018. A major theme emerging from public comment was the lack of support for allowing past acceptance history to determine whether or not transplant hospitals receive expedited offers. The Committee is proposing that transplant hospitals be allowed to "opt-in" to receive expedited liver offers. There was some discussion about creating a limit on the number of candidates eligible to receive expedited liver offers at each transplant hospital. However, the Workgroup eventually decided not to mandate such a limit at this time and allow transplant hospitals to make this determination based on the needs of their candidates. This proposal will require transplant hospitals to specify which of their candidates would be willing to accept an expedited offer. Workgroup members acknowledged that higher status candidates might not be ideal candidates for expedited liver offers, particularly if a liver is turned down late in the process due to organ quality. However, this will be left to the discretion of each transplant hospital. The Workgroup acknowledged that most transplant hospitals, including "non-aggressive" hospitals may initially opt-in to

[5] Descriptive data request prepared for Aug. 28, 2017 Workgroup conference call

[6] 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.

[7] https://optn.transplant.hrsa.gov/governance/public-comment/concept-paper-on-expedited-organ-placement/

receive expedited offers. However, the hope is that transplant hospitals will seriously evaluate the criteria for each of their candidates.

The Workgroup discussed the acceptance criteria that must be entered by the transplant hospital in order to participate in expedited placement. The Workgroup members unanimously supported proposing a requirement that transplant hospitals agree to allow any procurement team to recover the liver, if necessary. In a late turndown scenario, there is usually limited time for the center accepting the expedited liver offer to send a team to recover the liver. Allowing the surgical team currently in the donor operating room or a local recovery team to procure the organ will allow for a more efficient process.

The other liver donor criteria identified by the Workgroup include the following:

- Minimum and maximum age
- Maximum body mass index (BMI)
- Maximum distance from the donor hospital to transplant hospital
- Minimum and maximum height
- Percentage of macrosteatosis
- Minimum and maximum weight

While current liver donor acceptance criteria includes minimum and maximum age and weight, maximum BMI, and willingness to accept a DCD donor for local and import offers, this proposal will require transplant hospitals to specify this criteria, as well as several others, for each candidate in order to receive expedited liver offers. Transplant hospitals will also be allowed to enter the same or different criteria for donation after circulatory death (DCD) and donation after brain death (DBD) donors when they indicate the types of donors from which they would be willing to accept expedited liver offers.

This proposal will also require transplant hospitals to indicate the maximum distance from the donor hospital to the transplant hospital. The rationale for this being that transplant hospitals might not want to receive liver offers associated with a late turndown in the donor OR from certain distances. For example, a transplant hospital in New York might not want to receive expedited “late turndown in the OR” liver offers from a donor in California due to logistics or cold ischemia time (CIT).

Finally, this proposal will require transplant hospitals to indicate the percentage of macrosteatosis. This does not create a requirement for OPOs to perform liver biopsies or report this information. However, if the information is available at the time of the offer, it could provide useful information to help transplant hospitals make a decision on expedited liver offers and provide additional screening. Programming will allow OPOs to enter information on macrosteatosis if it is available at the time of the expedited liver offer.

OPOs Initiating Expedited Placement

This proposal does not establish a requirement for OPOs to initiate expedited placement if they can continue efforts to place the liver according to the match run. However, the proposal does establish policy requirements that address when OPOs can initiate expedited placement. The Spring 2019 public comment proposal established requirements that OPOs can initiate expedited liver placement efforts under two conditions. These include: 1) the donor being in the operating room, and 2) the host OPO being notified by the primary transplant hospital that the primary potential transplant recipient can no longer accept the liver. This proposal also adds a condition for DCD donors where the initiation of withdrawing life-sustaining medical support would qualify as one of the conditions. The rationale for this

being that DCD donors are not always in the operating room when the withdrawal of life-sustaining medical support has been initiated.

One of the main concerns raised during the January-March 2019 public comment period was that initiating expedited placement in the donor OR was too late in the process. Several OPOs and regions commented about how they currently have efficient processes for expedited placement. This includes contacting transplant centers well in advance of the scheduled donor OR to identify a center with a candidate available to accept a liver turned down in the OR. This process is not currently addressed in OPTN policy and may occur outside the standard backup offer process. If organ allocation does not follow the order of the match run it is known as an "out of sequence" allocation. This "out of sequence allocation" might be necessary in order to prevent a liver from not being utilized for transplant. However, an out of sequence allocation does require OPOs to provide a justification for review by allocation analysis staff and the MPSC.

One of the recommendations from public comment was to allow the expedited placement process to begin 2-3 hours prior to the scheduled donor organ recovery. The OPO Committee acknowledged that policy modifications would be required in order for this proposal to be accepted by the community. There was considerable discussion about how to modify policy language to accommodate this recommendation. In the end, the Committee agreed that it would be difficult to justify an arbitrary timeframe based on the scheduled donor organ recovery, which can change for a variety of reasons. The Committee agreed that allowing OPOs to see expedited liver candidates on the existing match run would be the most efficient approach. This will allow OPOs to evaluate the match run and make the necessary communications and arrangements in the event of a late turndown. The Committee also agreed that the conditions for initiating expedited placement outlined in this proposal need to be met before OPOs can send electronic expedited liver offers.

Expedited Liver Match Run

The Workgroup discussed the process for making expedited offers once the conditions have been met and the new screening has been applied to the original match run. The Workgroup members supported allowing transplant hospitals a limited amount of time to enter a response. The initial proposal set the response time limit at 20 minutes due to the urgency of placing expedited livers following a late turndown. During the initial public comment period there was considerable concern raised that 20 minutes was too short. The Committee discussed this comment and agreed to increase the time limit to 30 minutes.

The Workgroup discussed the number of transplant hospitals that could be included in a round of electronic offers. The Workgroup agreed that the number of electronic offers that can be sent should be increased from the current limits. Currently, the system provides the ability for each OPO to set limits for the maximum number of electronic organ offer notifications that can be sent to transplant center organ programs for local candidates. For non-local (regional/national) transplant centers, the maximum number of notifications is set by the system at 3 pre-recovery and 5 post-recovery. With this proposal, the Workgroup would like to allow flexibility for OPOs to specifically choose how many transplant hospitals can receive offers in this expedited system, therefore creating a new notification limit collection field specifically for expedited offers.

In addition, the Workgroup discussed who would receive an expedited liver offer. The recommendation has been made to create a new on-call representative in the contact management section within DonorNet that would specifically receive expedited liver offers. Providing an expedited specific representative on-call may allow for a faster decision within a shorter decision-making time period. This

would not be mandatory option if transplant hospitals believe that their current process of receiving organ offers is sufficient to meet their needs.

The following is an overview of how the process may be operationalized:

The expedited placement pathway will use the following rules:

- Must have an acceptance on the current liver match run.
- Electronic offers will be sent using the current match run.

When the host OPO changes a previous acceptance for the primary potential transplant recipient to a refusal, the following questions could be displayed:

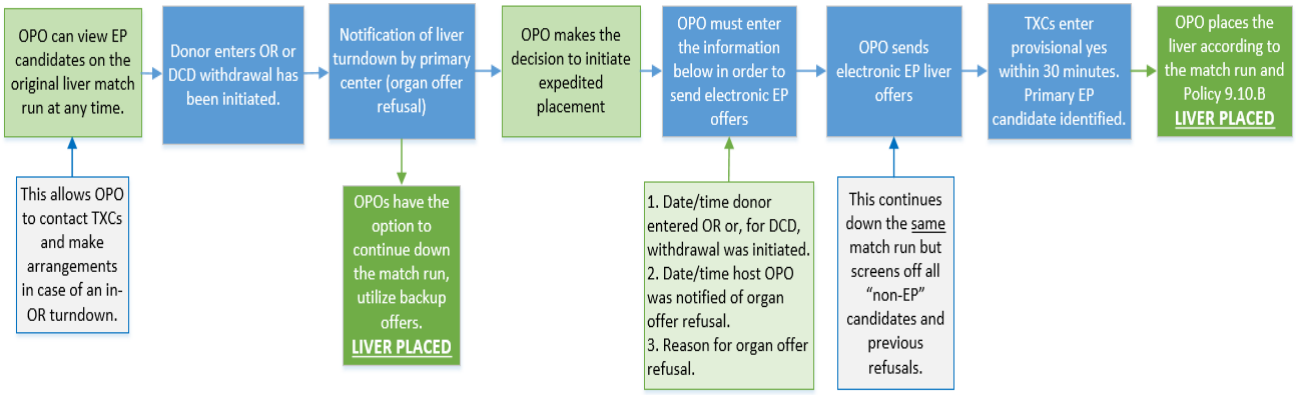
1. Has the donor entered the OR or DCD withdrawal occurred?
    - If no, the OPO will enter the refusal and save.
    - If yes, the OPO will answer question #2.
2. Would you like to initiate expedited placement?
    - If no, the OPO will enter the refusal and save.
    - If yes, the OPO will be required to enter the following information:
        - Date/time donor entered the OR. For DCD donors, date/time withdrawal of support was initiated. *Note:* DCD donor fields will be available based on information entered in the donor record.
        - Date/time host OPO notified of turndown.
    - The OPO user will then select "save and initiate expedited placement" and the match results will change and dynamic screening will occur.

Additional rules to be applied when the expedited offer process is initiated:

- Existing provisional yes responses for candidates who have opted-in to receive expedited liver offers will remain on the match run. These candidates will receive another notification for an expedited liver offer.
- Candidates with a previous provisional yes response who have not opted-in to receive expedited liver offers will be bypassed.
- Candidates who have already refused will maintain their refusal regardless of whether or not they have opted-in to receive expedited liver offers.
- Candidates who have not opted-in to receive expedited liver offers, and who have not received an offer, will be bypassed.
- Candidates who should receive expedited liver offers will remain on the match run.
- All new electronic offers will have 30 minutes to respond. If no response is entered, the system will automatically enter a response of "exceeded time limit."

The Workgroup recognized that transplant hospitals will need to understand that provisional yes responses to expedited liver offers are not a guarantee they will eventually receive the liver. Additionally, these offers will be made based on the deceased donor information available at the time of the offer. *Policy 2.11: Required Deceased Donor Information* addresses the information that needs to be provided for each potential deceased donor. The urgent need to get the liver placed does not allow time for transplant hospitals to request additional information. At the end of the 30 minute time limit, the OPO must place the liver with the candidate with a provisional yes response that appears highest on the match run. **Figure 1** outlines the proposed process for the expedited placement of livers. OPOs can send additional expedited offers as needed to get the liver placed.

Figure 1: Proposed Expedited Liver Placement Process



Additional Policy Changes

During policy development, UNOS staff conducted a comprehensive review of all OPTN policies to identify current policies that might conflict with the proposed policy changes. As a result of this review, the Committee proposes modifications to the following policies:

1.2 Definitions - Organ Offer Acceptance – The only proposed change is a minor language modification.

5.3.D: Liver Acceptance Criteria – This policy lists additional liver acceptance criteria that liver transplant programs may enter for liver candidates. The Committee added a reference to *Policy 9.10.A: Expedited Placement Acceptance Criteria* in this section of policy.

5.6.B: Time Limit for Review and Acceptance of Organ Offers – This policy addresses the time limit to accept or refuse organ offers for primary potential transplant recipients. This includes one hour for the initial primary potential recipient and 30 minutes for candidates with a previous provisional yes who become the primary offer. The process for responding to expedited liver offers requires transplant hospitals to only respond with a provisional yes within 30 minutes in order to be eligible to receive the expedited liver offer. Since this process is different, the Committee is proposing language stating that this policy does not apply to expedited liver offers.

Other Considerations for System Efficiency but not Required Policy

The Workgroup discussed several additional issues related to expedited placement. While these are important topics, the Workgroup and the Committee determined that these should **not** be part of the proposed policy requirements.

Delaying Cross Clamp

The Workgroup acknowledged that delaying cross clamp whenever possible could provide benefits such as decreased cold ischemia time and allowing additional time for logistics such as reallocation and transportation. Therefore, the Workgroup suggests delaying cross clamp by one hour to accommodate expedited placement, if the donor is hemodynamically stable.

Transportation Logistics

The Workgroup acknowledged that transportation logistics will have an impact on the expedited placement of livers. It is suggested that the host OPO assist the accepting transplant hospital with additional air and ground transportation if needed.

Use of Third-Party Call Centers

It is suggested that transplant hospitals develop processes that allow communication of expedited offers directly to the decision makers.

These three items are suggestions only, not part of the proposed policies, which the Workgroup believes could enhance efficiency of expedited placement. The OPO Committee may consider issuing formal guidance at a later date based on post-implementation evaluation if the proposed policy language is approved.

Compliance with National Organ Transplantation Act (NOTA) and Final Rule

The OPTN Final Rule[8] sets requirements for allocation policies developed by the OPTN. This proposal complies with the following aspects of the Final Rule:

- Shall be based on sound medical judgment by allowing transplant programs to determine which of their candidates might benefit from a liver turned down late in the process.
- Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e).
- Shall be designed to avoid wasting organs by establishing an efficient placement process for livers turned down late in the process.
- Shall be designed to promote patient access to transplantation by establishing a system where candidates willing to accept expedited livers offers will have access to such offers.
- Shall be designed to promote the efficient management of organ placement by establishing a process for OPOs to send expedited offers when livers are turned down late in the process. There may be some concern raised that the proposed policies will lead to a less efficient system and potentially increase incidents of organs recovered but not transplanted by creating additional steps for expedited placement. However, the Workgroup and the Committee has worked diligently to propose a system that will be as efficient as possible while also promoting access based on the medical judgment of the candidate's healthcare team.

Additionally, this proposal is aligned with the following OPTN Strategic Plan goals:

1. *Increase the number of transplants:* This proposal has the potential to increase the number of transplants by standardizing expedited placement practices across OPOs and allowing expedited liver placement to occur according to OPTN policy. There is also the potential to reduce the number of transplants if the final policy requirements are cumbersome and create barriers for OPOs during expedited placement.
2. *Improve equity in access to transplants:* This proposal could increase access to transplants by requiring OPOs to offer organs to transplant hospitals that were previously bypassed during expedited placement.
3. *Promote the efficient management of the OPTN:* This proposal creates an expedited placement process in policy that has not existed until now. This proposal may increase the efficient management of the OPTN by reducing the number of cases being reviewed by UNOS staff and the MPSC.

[8] 42 C.F.R §121.8

Implementation

Logistics

This proposal will require programming in UNet[sm].

- A new field will be added to the acceptance criteria section on the Liver Candidate record in Waitlist[sm] to allow centers to distinguish specific candidates willing to accept expedited liver offers as part of a candidate's liver acceptance criteria. In addition, transplant programs will have to designate their macrosteatosis percentage acceptance levels on the Waitlist. Macrosteatosis percentage will also be added to the Liver Biopsy section in the Organ Data tab within DonorNet® for OPO entry. Transplant programs will be required to specify on a candidate-by-candidate basis which specific expedited placement criteria they would be willing to accept.
- New designation fields will appear on a liver match run distinguishing which candidates are willing to accept an expedited liver offer. Upon refusal of a previously accepted liver, a new workflow on the original match run will request specific information from the OPO user regarding the expedited liver placement rules set forth in policy: date/time the host OPO was notified of refusal by the primary transplant hospital, date/time the donor has either entered the operating room or withdrawal of support has occurred for a DCD donor, and macrosteatosis if not entered into the Organ Data tab. After this limited required information has been entered, and the policy criteria are met, new screening will appear on the original liver match run. This screening will adjust the match run specific to those candidates willing to accept an expedited liver match and who do not screen for macrosteatosis percentage.

The programming for this proposal will be a very large effort.

The Committee plans to work with the UNOS Professional Education department to develop educational materials for this proposal if approval by the Board of Directors. Communications will be sent to the community to promote awareness related to policy and system changes in advance of implementation.

Member Burden

Transplant Hospitals

This will impact how livers are offered to transplant hospitals during expedited placement. Transplant hospitals should develop processes to ensure that decision makers are aware of abbreviated timeframe to accept these offers. Transplant hospitals will need to be aware of the acceptance criteria information that must be entered for liver candidates in order to receive expedited liver offers.

OPOs

This will impact how OPOs allocate livers using expedited placement. OPO staff will need to participate in educational offerings to prepare for this change.

Will this proposal require members to submit additional data?

Yes, transplant centers will be required to enter additional liver acceptance criteria in order to participate in expedited placement, as outlined in *Policy 9.10.A: Expedited Placement Acceptance Criteria*. This includes criteria already entered for liver candidates such as age, height, weight, and BMI. They will also be required to enter the percentage of macrosteatosis and agreement to accept a liver recovered by any procurement team. This information will need to be entered for each type of donor (DCD and DBD) from which they are willing to accepted expedited liver offers.

Prior to initiating expedited placement for a liver, OPO staff will be required to report when the donor entered the OR, or when withdrawal of support has occurred for DCD donors and when they were notified that the previously accepted liver offer was refused.

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. The collection of official OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval by the federal Office of Management and Budget (OMB). The OMB approval process may impact the implementation timeline.

Evaluation

Members Compliance

In addition to the monitoring described below, all policy requirements and data entered in UNet℠ may be subject to OPTN review, and members are required to provide documentation as requested.

UNOS staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy. Staff will also continue to inquire with OPOs when they enter bypass codes in order to allocate the organ out of sequence on the match run. If a transplanted liver is allocated using the proposed process for expedited placement of livers, staff will request documentation to verify the accuracy of the dates and times entered to initiate the expedited placement process according to *Policy 9.10.B Expedited Liver Offers*.

Committee evaluation post-implementation

The OPTN will assess the impact of these policy changes at 6-months and 12-months post implementation. Analyses beyond 12-months will be performed at the request of the Committee.

There is currently no accurate way in the OPTN system to assess how often a liver is turned down in the OR. As a result, much of the analyses will be “point forward” analyses and can be used as a benchmark to assess changes in the future. The OPTN will perform analyses to study the following:

- Overall
    - The number and percent of in-OR refusals
    - The number and percent of in-OR refusals that result in a transplanted liver
    - The number and percent of in-OR refusals that result in a liver recovered but not transplanted

- The reasons reported for the in-OR refusal
- The demographics of liver donors that have an in-OR refusal

• By OPO

- The number and percent of in-OR refusals
- The number and percent of in-OR refusals that result in a transplanted liver
- The number and percent of in-OR refusals that result in a liver recovered but not transplanted
- The reasons reported for the in-OR refusal

• By Transplant Center

- The number and percent of livers refused in-OR
- Refusal reasons for livers refused in-OR
- Distribution of candidates listed as willing to accept an expedited (in-OR) liver
- Number and percent of expedited acceptances transplanted
- Number and percent of expedited acceptances not transplanted
- Acceptance rates for expedited (in-OR) liver offers

The OPTN will assess the overall impact of these policy changes using a pre vs. post analysis at 6-months and 12-months after implementation. Analyses beyond 12-months will be performed at the request of the Committee.

• Liver utilization rates pre vs. post implementation

• Liver discard rates pre vs. post implementation

• Liver transplant volumes pre vs. post implementation

• Out of sequence liver placements pre vs. post implementation

Summary

This proposal establishes a system that allows OPOs to send electronic expedited liver offers to transplant hospitals with candidates willing to accept expedited liver offers. The intent of this proposal is to create transparency in how expedited livers are placed while also increasing access to liver offers for candidates who might otherwise be bypassed when OPOs need to quickly place livers following a turndown late in the process.

The Committee will consider all public comment feedback in October 2019 to determine if additional modifications need to be made to the policy language. The Committee would also appreciate feedback on the following questions:

1. Does this proposal improve the process for expediting the placement of livers turned down in the donor OR?
2. One of the main concerns raised during the previous public comment was that initiating expedited placement in the donor OR was too late in the process. Does allowing OPOs to identify expedited liver candidates on the original liver match run address that concern?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Organ offer acceptance

When the transplant hospital notifies the host OPO that it ~~they~~ accepts the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.

5.3.D Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN Contractor.

Liver transplant programs may also specify additional liver acceptance criteria, including any of the following:

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. Acceptance criteria for expedited offers as outlined in *Policy 9.10.A: Expedited Placement Acceptance Criteria*
~~3.~~ 4. If a blood type O candidate will accept a liver from a deceased donor with blood type A, non- A1
~~4.~~ 5. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
~~5.~~ 6. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
~~6.~~ 7. If a candidate will accept a liver for other methods of hepatic support
~~7.~~ 8. If a candidate is willing to accept a segmental graft
~~8.~~ 9. If a candidate is willing to accept an HIV positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule

5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to Policy 2.11: Required Deceased Donor Information, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with either of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with either of the following:

- An organ offer acceptance

- An organ offer refusal

9.10 Expedited Placement of Livers

9.10.A Expedited Liver Placement Acceptance Criteria

In order for a liver candidate to receive expedited offers as outlined in *Policy 9.10.B: Expedited Liver Offers*, the transplant hospital must report *all* of the following information to the OPTN Contractor:

1. Agreement to accept a liver recovered by any procurement team
2. The following liver acceptance criteria:
    - Minimum and maximum age
    - Maximum body mass index (BMI)
    - Maximum distance from the donor hospital
    - Minimum and maximum height
    - Percentage of macrosteatosis
    - Minimum and maximum weight

9.10.B Expedited Liver Offers

The host OPO or the Organ Center is permitted to make expedited liver offers if *both* of the following conditions are met:

1. The donor has entered the operating room or, in the case of a DCD donor, withdrawal of life sustaining medical support has been initiated, whichever occurs first.
2. The host OPO or Organ Center is notified by the primary transplant hospital that the primary potential transplant recipient will no longer accept the liver.

Prior to sending expedited liver offers, the host OPO or Organ Center must report *all* of the following information to the OPTN Contractor:

1. Date and time donor entered the operating room or withdrawal of life sustaining medical support was initiated, whichever occurs first.
2. Date and time host OPO was notified by the primary transplant hospital that they will no longer accept the liver offer for the primary potential transplant recipient.
3. Reason for organ offer refusal by the primary potential transplant recipient.

Expedited liver offers will be made to potential transplant recipients on the match run who are eligible to receive expedited liver offers as described in *Policy 9.10.A: Expedited Liver Placement Acceptance Criteria.*

Transplant hospitals must accept an expedited offer within 30 minutes of notification to be eligible to receive the liver. Once this time limit has expired, the host OPO or Organ Center must place the liver with the potential transplant recipient with the provisional yes that appears highest on the match run.