OPTN | UNOS

Public Comment Proposal

Improving the Efficiency of Organ Placement

OPTN/UNOS Organ Procurement Organization Committee

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Contents

Improving the Efficiency of Organ Placement

Affected Policies:	*Policies 2.2: OPO Responsibilities, 2.11: Required Deceased Donor Information, and 5.6: Receiving and Accepting Organ Offers*
Sponsoring Committee:	*Organ Procurement*
Public Comment Period:	*July 31, 2017 – October 2, 2017*

Executive Summary

On April 30, 2007, mandatory use of DonorNet® began with the goal to facilitate and expedite organ placement using an electronic organ placement system. This system allows organ procurement organizations (OPOs) to electronically notify transplant hospitals about organ offers and provide donor information. During recent discussions and proposals that seek to increase the broader sharing of organs, the transplant community has acknowledged the need to make improvements to the organ placement system in order to place organs more efficiently.

Many factors lead to inefficiencies in the organ allocation process. Some of these, such as logistical issues, are difficult to control while OPOs and transplant programs can control other issues, such as communication. This proposal is the first step to improve the organ placement process by proposing the following:

- Reduce the current time limits for responding to organ offers
- Establish a new time limit for the primary transplant hospital to make a final decision on organ offers
- Limit the number of organ acceptances for one candidate at any given time
- Require OPOs to manage organ acceptances in real time.

This proposal will also address the required deceased donor information by simplifying the language and reducing redundancies and inconsistencies in *Policy 2.11: Required Deceased Donor Information.*

This proposal primarily supports OPTN/UNOS Strategic Goal 1: Increasing the number of transplants by improving the placement of organs and potentially reducing organ discards, leading to an overall increase in the number of transplants.

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

Members are asked to comment on both the immediate and long-term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community.

What problem will this proposal address?

The purpose of this proposal is to improve the placement of organs thus minimizing or eliminating any organ discards related to inefficiencies in the current system. As the OPTN moves forward with proposals to increase the broader sharing of organs, members have expressed concerns that any inefficiencies in the current system could be exacerbated with larger geographic sharing areas. Since the implementation of the revised kidney allocation system (KAS) there has been an increase in the number of kidneys shared beyond the DSA level[1]. Additionally, recent heart[2] and liver allocation[3] proposals have proposed increased sharing over a broader geographic area.

Inefficient organ placement can also lead to decreased quality of organs, especially when attempts to place organs occur post-procurement or when late reallocation occurs after an organ acceptance has been rescinded. Organ placement can be delayed as OPOs work through the lists of provisional yes acceptances. Increased donor case time can also have a negative impact on donor families.

This proposal is the first step to improve the organ placement process by reducing the current time limits for responding to organ offers, establishing a new time limit for the primary transplant hospitals to make a final decision on organ offers, limiting the number of organ acceptances for one candidate at any given time, and requiring OPOs to manage the organ acceptances in real time.

Why should you support this proposal?

The proposed policy is a step towards a more efficient organ placement system. These changes, as well as future efforts, will improve the current system as well as improve a system in which broader sharing of organs is expanded. Efficient organ placement can benefit both OPOs and transplant programs by potentially shortening donor case times and getting the right organs to the right candidates at the right time in the most efficient manner. Shorter case times can also provide a benefit to donor families by not prolonging the donor management process while organ placement continues.

How was this proposal developed?

On April 30, 2007, mandatory use of DonorNet® began with the goal to facilitate and expedite organ placement using an electronic organ placement system. This system allows OPOs to share donor information and electronically notify transplant hospitals about organ offers. The original intent of electronic notifications was to reduce the organ placement time by obtaining organ offer refusals from transplant centers. This would allow the OPOs to focus their efforts on contacting transplant centers that are interested in the organ offer. Currently, when organ offers are sent electronically there are two offer responses available for transplant centers: Refuse and Provisional Yes. Transplant centers will enter a provisional yes acceptance if they are interested in accepting the organ or receiving more information about the organ.

The OPTN Final Rule[4] states that one of the performance goals for the allocation of organs is “distributing organs over as broad a geographic area as feasible.” In addition to recent changes to kidney allocation, there have been discussions to increase the broader sharing within the other organ systems. One of the goals of the new kidney allocation system (KAS), which was implemented in December 2014, was to address the variability in access to transplantation by candidate blood type and geographic location.[5] The Thoracic Organ Transplantation Committee recently proposed allocation changes to provide the most medically urgent candidates access to donors from a broader geographic area.

[1] https://www.transplantpro.org/wp-content/uploads/sites/3/KAS_12month_analysis.pdf

[2] https://optn.transplant.hrsa.gov/governance/public-comment/modify-adult-heart-allocation-2016-2nd-round/

[3] https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/

[4] OPTN Final Rule

[5] https://optn.transplant.hrsa.gov/media/2159/equity_in_access_report_201705.pdf

During early discussions regarding redistribution proposals, the Liver and Intestinal Organ Transplantation Committee convened a subcommittee to examine ways to increase utilization of livers. Members felt that any inefficiencies in the current organ placement system could be exacerbated with larger geographic sharing areas. Similarly, the implementation of KAS has increased the number of kidneys shared beyond the donor service area (DSA) level. Further discussions led to the acknowledgement that the problem exists across all organ types and should be addressed simultaneously.

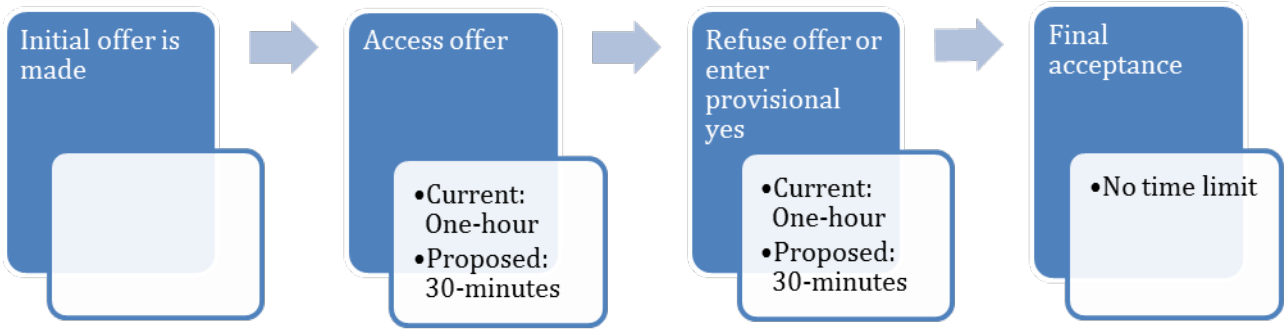
The OPO Committee formed a joint work group made up of representatives from the organ-specific committees, Transplant Coordinators Committee, and the Operations and Safety Committee. The work group identified their charge to evaluate and recommend policy and system changes that will increase the efficiency of organ allocation, placement and acceptance to prevent the loss or misallocation of solid organs. They also defined inefficient organ placement as "the breakdown of the normal allocation processes that results in the delay of the donation process, deviation from the match run, or the loss of an organ for transplant."

The work group identified a list of barriers to efficient organ allocation. These include:

1. Time limits for responding to organ offers
2. Organ offer acceptance limits
3. DonorNet limitations
4. Number of simultaneous offers that can be sent out at one time
5. Use of provisional yes acceptances
6. Transplant center acceptance criteria
7. Transplant center acceptance practices

This proposal will address the first two barriers while the work group continues to address the remaining barriers. This continued work could lead to additional policy changes as well as changes to DonorNet.

Time Limit for Responding to Organ Offers
The work group agreed that a first step towards improving the organ placement process is to reduce the time limits for responding to electronic offers. Policy 5.6.B (Time Limit for Acceptance) states that a "transplant hospital must access the deceased donor information in the match system within one hour of receiving the initial organ offer notification." Policy allows transplant hospitals an additional hour to refuse the offer or enter a provisional yes after accessing the deceased donor information.



Most of the work group members supported shortening the response times and agreed that the current time limits for responding to electronic organ offers could be reduced from 1 hour to 30 minutes. This includes the one hour time limit for transplant centers to access the organ offer and the one hour time limit for transplant centers to enter a refusal or provisional yes response. The work group's review of data showed that responses are received within 30 minutes of initial notification (**Figure 1**) and evaluation (**Figure 2**) across all organs in 90% of cases.

Figure 1. Transplant program time from offer notification to evaluation, by organ type.

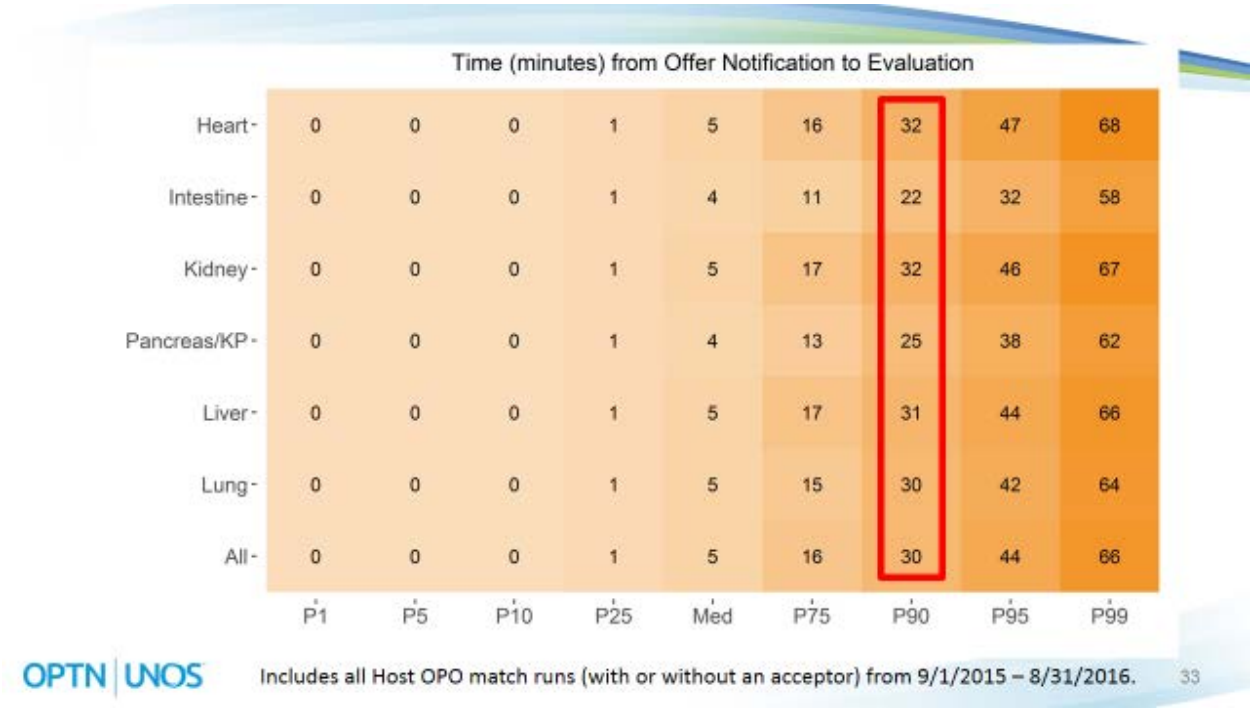
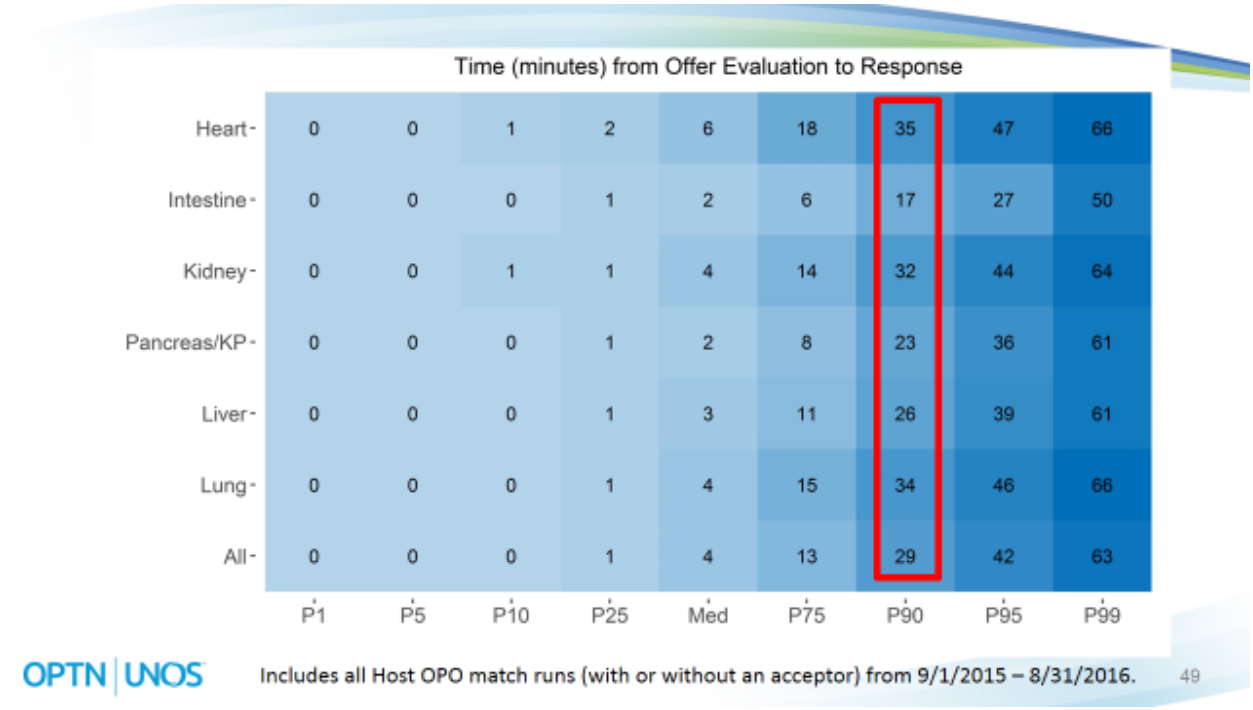


Figure 2. Transplant program time from offer evaluation to response, by organ type.



Additionally, the work group agreed that an additional time limit should be created for transplant programs to make a final decision on an offer once the OPO notifies them that their candidate is now primary. Current OPTN policy does not address how long a transplant center can take to make this final decision. This can slow down the placement process as OPOs work their way down the match run to address the provisional yes responses. The work group agreed that policy language should be added that makes it permissible for the OPO to move on to the next candidate if a final decision is not made within a certain

timeframe. This final decision is either an organ offer acceptance or an organ offer refusal. The work group agreed that this should not be a mandate for OPOs to move to the next candidate on the list; there still needs to be communication between the transplant hospitals and OPOs in an effort to place organs according to the match run. If OPOs have provided all the information required by policy, transplant centers should be able to make a final decision on the organ offer. The work group members acknowledged that there can be situations where surgeons are in the operating room or more time is needed to contact the recipient. However, these are examples of operational issues that slow down the placement process and should not be allowed to hold up a final decision for extended time periods.

Because this proposal addresses provisional yes, organ offer acceptance, and organ offer refusal, the Committee is proposing policy definitions for these terms.

Limiting Offer Acceptances for the Same Organ Type at the Same Time

This proposal limits the number of offers for the same organ type that transplant hospitals can accept for a single candidate at one time. The practice of having multiple offer acceptances can lead to late declines which cause logistical issues for OPOs resulting in forced organ reallocations. While this can occur across organ types, work group members acknowledged that this problem primarily occurs with liver offers. The OPTN does not currently collect data on late turndowns; however, the work group acknowledged that it is a problem that could be mitigated by this proposal. OPO representatives on the work group provided anecdotal examples of waiting a significant number of hours for recovery teams to arrive for organ procurement, only to have the teams turn down the organ to accept a "better offer." This increase in donor case time can negatively impact organ quality as well as donor families. The examples below illustrate how this problem occurs in the clinical setting:

OPO A makes a liver offer to Patient X at Center Y. Center Y accepts the organ and sends a team to recover the liver. This process takes multiple hours, during which time Patient X receives additional offers from OPO B and OPO C. When Center Y arrives on site for organ recovery, they are notified that one of the other offers is potentially a higher quality organ and they decline the liver for Patient X. OPO A must then start the placement process over again to find a suitable candidate for the liver, but now the donor is in the operating room.

OPO A makes a liver offer to Patient X at Center Y. OR time is set and arrangements are made to move the donor to the OR. Patient X then gets another offer and Center Y wants to delay OR until visualization of the second liver to make sure it isn't better than the offer from OPO A.

The work group initially discussed proposing a limit of two "provisional yes" acceptances but eventually agreed that an appropriate first step would be to limit actual organ acceptances. This will not prevent transplant programs from receiving additional offers, but will limit the number of organ offer acceptances for one candidate at any given time by organ type. The work group also agreed to apply this limit to all organ systems. Finally, the work group agreed that in order for this proposed change to work, all OPOs will need to manage the organ acceptances in real time. OPO representatives on the work group noted that if there is a benefit to managing the acceptances in real time most OPOs would be willing to change their practices.

Changes to Policy 2: Deceased Donor Organ Procurement

Policy 2.2 OPO Responsibilities - The Committee is proposing the following modifications to the policy:

- Requiring host OPOs to ensure all the deceased donor information is provided according to *Policy 2.11: Required Deceased Donor Information*.
- Removing required deceased donor information that has been moved to Policy 2.11

Policy 2.11 Required Deceased Donor Information - While discussing the time limits for responding to organ offers, the work group agreed it was important to address the required deceased donor information.

The policy outlines the OPO requirements for providing donor information to the transplant programs. The work group initially discussed creating a comprehensive list of required information to include the required fields in DonorNet. However, it was determined that such an extensive list would be difficult to manage and keep updated. It would also reduce the flexibility for OPOs and transplant programs to share the necessary information on a case-by-case basis to best determine donor and recipient suitability. The work group identified redundancies and inconsistencies in policy. They agreed to simplify and reorganize the list of required donor information. This includes creating broad categories for certain donor information.

Below is a summary of the proposed changes:

Policy 2.11 - *Donor medical history* will include the following information currently listed in Policy 2.11.A through 2.11.E

- Date of admission for the current hospitalization
- Pertinent past medical or social history including pancreatitis
- Smoking history
- Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
- Current medication and transfusion history
- History of medical treatment in hospital including vasopressors and hydration
- Current history of abdominal injuries and operations, including pancreatic trauma
- Cardiopulmonary, social, and drug activity histories
- Details of any documented cardiac arrest or hypotensive episodes
- Indications of sepsis
- Vital signs, including blood pressure, heart rate and temperature

Policy 2.11 - *Donor behavioral and social* history will include the following information currently listed in Policy 2.11.A through 2.11.E

- Social history and drug use
- Alcohol use
- Relevant past history and social history
- Pertinent past medical or social history including pancreatitis

Policy 2.11 – *Organ anatomy and recovery information* will include the following information currently listed in Policy 2.11.A through 2.11.E

- Recovery medications
- Recovery blood pressure and urine output information
- Type of recovery procedure, flush solution and method, and flush storage solution
  Warm ischemia time and organ flush characteristics

Policy 2.11 – *Donor evaluation information to include laboratory testing, radiologic results and injury to the organ* will contain the specific lab tests currently listed in Policy 2.11.A through 2.11.E

Policy 2.11 – *Donor management* will contain the following information currently listed in Policy 2.11.A through 2.11.E

- Vital signs, including blood pressure, heart rate and temperature

Finally, the work group discussed the requested information listed in *Policy 2.12: Requested Deceased Donor Information.* Since the information included in this section of policy is not required, the work group agreed that it could be removed from policy. The work group agreed that a guidance document should be developed that will outline best practices from both a transplant hospital and OPO perspective. For example, what type of donors might require additional tests outside of a normal donor evaluation? The work group plans to develop this guidance document in time for the public comment period beginning in January 2018.

Ongoing Work

As previously mentioned, this proposal is the first step to improving the organ placement system. The work group will continue its work to address the other barriers identified by the work group. The work group will continue to work with the UNOS Customer Advocacy department to propose changes to DonorNet to provide better tools for OPOs and transplant centers to communicate about organ offers. The current system is not dynamic and does not provide the flexibility to adjust to the changing environment within each organ offer. These changes will be managed outside of the normal policy development process because they are not requirements. Some of the recommendations for DonorNet changes include:

- Notification when transplant centers when they become primary
- Notification when "critical" donor information is added or changed (organ-specific)
- Notification when certain attachments are available
- Ability to view films
- Ability to "follow a donor" – this will be an iterative process starting with O.R. time to test this functionality
- Better capture information such as current medications, final infectious disease reports, vasopressor use, and blood transfusion

The work group will also revisit the issue of provisional yes acceptances and begin to address transplant hospital acceptance criteria and practices. Addressing these issues will continue the effort to improve the placement of organs.

How well does this proposal address the problem statement?

As noted earlier in this proposal document, inefficient organ allocation can lead to organ discards, impact the quality of organs, and negatively impact donor families with the increase in donor case time. With the growing possibilities of broader sharing for all organs, it is imperative to make improvements to the current system of organ placement. This proposal is the first step to improve the organ placement process by reducing the time limits for responding to organ offers, establishing a new time limit for transplant hospitals to make a final decision on organ offers, and limiting the number of organ acceptances for one candidate.

Which populations are impacted by this proposal?

This proposal will have a positive impact on candidates and donor families. Improving the efficiency of organ placement will help ensure that the right organs get to the right candidates in a timely manner. This also has the potential to benefit donor families by reducing the length of donor cases.

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: This proposal will improve the placement of organs and decrease organ discards, leading to an overall increase in the number of transplants.

Improve equity in access to transplants: There is no impact to this goal

Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal

Promote living donor and transplant recipient safety: There is no impact to this goal

Promote the efficient management of the OPTN: There is no impact to this goal

How will the OPTN implement this proposal?

As these policy changes affect receiving and accepting organ offers, an educational program addressing the member impact will likely be necessary.

This proposal will require programming in UNet^{SM}.

- For reducing the time limits to respond to organ offers, the automated notifications will need to be modified:
    - Notification of organ offer – Currently, if the system is unable to reach the primary contact, the system automatically attempts to notify the secondary contact by voice or text after 20 minutes. If the secondary contact cannot be reached, the system will automatically attempt to notify both the primary and secondary contacts again by voice or text. These automated notifications will be change to 10 minutes and 20 minutes.
- For the limit on the number of organ offer acceptances, the system will notify OPOs and transplant centers that an acceptance limit has been reached and provide them with the ability to turn down one of the previous two acceptances.

How will members implement this proposal?

This proposal will impact transplant hospitals and OPOs.

Transplant Hospitals

This proposal will require transplant hospitals to evaluate their processes for receiving organ offers. The reduction in time limits could impact those organizations that currently use third-party vendors to receive organ offers. Transplant hospitals need to be aware of the new proposed one-hour limit for making a final decision once their candidate becomes the primary offer. Finally, transplant hospitals need to be aware that only two organ offer acceptances will be allowed for one candidate (for the same organ type) at the same time.

OPOs

This proposal will require OPOs to indicate “organ placed” in DonorNet in real time to ensure that the proposed organ offer acceptance limit meets its intended goal. OPOs should also review the changes to *Policy 2.11: Required Deceased Donor Information* in order to ensure timely and accurate reporting of donor information.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection. This proposal will reduce the data burden by eliminating certain required information such as echocardiograms and electrocardiograms for deceased lung donors.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

The proposed language will not change the routine allocation monitoring of OPTN members. UNOS allocations’ 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 policy requirements. They will continue to investigate potential policy violations.

The following change to routine site surveys will occur based on the proposed language:

Policy 2.11.C: Required Information for Deceased Heart Donors

At OPOs, site surveyors will review a sample of deceased heart donor records for documentation of results or other evidence that an echocardiogram was performed.

Under current Policy 2.11.C, site surveyors look for results or other evidence that *either* a cardiology consult *or* an echocardiogram was performed.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The OPTN will assess the 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.

The OPTN will monitor the policy change that establishes new time limits throughout the organ offer process by studying the following:

- The distribution of times from:
  - Offer notification to evaluation
  - Offer evaluation to response
  - Primary offer with all required data in DonorNet to final decision (only post implementation)
- Usage of the bypass code for exceeding response time limits

Further, the OPTN will monitor the policy change to limit the number of concurrent offers a transplant center can accept for a single candidate in the following ways:

- Determine that the system is only allowing two concurrent final acceptances for a candidate
  - Monitor the first month post implementation
- Determine how often candidates have two concurrent final acceptances
  - Assess at 6 months, 12 months, and 18 months post implementation

Policy Language

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

Policy 1.2 Definitions

O

Organ offer acceptance

When the transplant hospital notifies the host OPO that they accept the organ offer for an intended recipient, pending review of organ anatomy.

Organ offer refusal

When the transplant hospital notifies the OPTN Contractor or the host OPO that they are declining the organ offer.

P

Provisional yes

When the transplant hospital notifies the host OPO that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ.

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the c~~C~~linical management of the deceased donor.
8. En~~As~~suring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.

11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt ~~to enable complete and accurate evaluation of donor suitability by transplant programs~~:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    ~~f. Human leukocyte antigen (HLA) type~~
    ~~g. Donor evaluation and management~~
    ~~h. Donor medical and behavioral history~~
    ~~i. Organ intraoperative findings~~
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.11 Required Deceased Donor Information

The host OPO must ~~obtain~~ report to the OPTN Contractor upon receipt *all* of the following information for each potential deceased donors:

1. Age
2 Diagnosis (or cause of brain death)
~~3. Sex~~
3. Donor behavioral and social history
4. Donor management information
5. Donor medical history
6. Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ
7. Ethnicity
8. Height
9. Organ anatomy and recovery information
11. Sex
12. All vital signs, including blood pressure, heart rate, and temperature
13. Weight

The potential transplant program team must have the opportunity to speak directly with responsible onsite OPO donor personnel to obtain current information about the deceased donor's physiology.

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

~~1. Date of admission for the current hospitalization~~
~~2. Donor name~~
~~3. Donor ID~~
~~4. Ethnicity~~
~~5. Relevant past medical or social history~~
~~6. Current history of abdominal injuries and operations~~
~~7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria~~
~~8. Current medication and transfusion history~~
~~9.~~1. Anatomical description, including number of blood vessels, ureters, and approximate length of each
2. Biopsy results, if performed
~~10.~~ 3. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
~~11. Indications of sepsis~~
~~12.~~ 4. Injuries to or abnormalities of blood vessels, ureters, or kidney
5. Kidney perfusion information, if performed
~~13. Assurance that final blood and urine cultures are pending~~
~~14. Final urinalysis~~
~~15. Final blood urea nitrogen (BUN) and creatinine~~
~~16. Recovery blood pressure and urine output information~~
~~17. Recovery medications~~
~~18. Type of recovery procedure, flush solution and method, and flush storage solution~~
~~19. Warm ischemia time and organ flush characteristics~~

2.11.B Required Information for Deceased Liver Donors

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

~~1. Donor name~~
~~2. Donor ID~~
~~3. Ethnicity~~
~~4. Height~~
~~5. Weight~~
~~6. Vital signs, including blood pressure, heart rate and temperature~~
~~7. Social history, including drug use~~
~~8. History of treatment in hospital including current medications, vasopressors, and hydration~~
~~9. Current history of hypotensive episodes, urine output, and oliguria~~
~~10. Indications of sepsis~~
~~11. Aspartate aminotransferase (AST)~~
~~12. Bilirubin (direct)~~
1. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program
~~13.~~ 2. Other laboratory tests within ~~the past~~ 12 hours of the offer ~~including~~:
    a. Alanine aminotransferase/asparate aminotransferase (ALT/AST)
    b. Alkaline phosphatase
    c. Total and direct bilirubin
    ~~d. Creatinine~~

- ~~e. Hemoglobin (hgb) and hemocrit (hct)~~
- ~~f~~d. International normalized ratio (INR) or Prothrombin (PT) if INR is not available~~, and~~
  e. P~~p~~artial thromboplastin time (PTT)

~~g. White blood cell count (WBC)~~

3. Pre-procurement biopsy results, if performed
4. Pre-procurement CT imaging results, if performed

~~14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program~~

~~If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.~~

2.11.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

~~1. Height~~
~~2. Weight~~
~~3. Vital signs, including blood pressure, heart rate, and temperature~~
~~4. History of treatment in hospital including vasopressors and hydration~~
~~5. Cardiopulmonary, social, and drug activity histories~~
~~6. Details of any documented cardiac arrest or hypotensive episodes~~
~~7.~~1.12-lead ~~interpreted~~ electrocardiogram interpretation, if available
~~8.~~2. Arterial blood gas results and ventilator settings
~~9.~~3. Cardiology consult, if performed ~~or echocardiogram, if the hospital has the facilities~~
4. Echocardiogram~~, if the hospital has the facilities~~ ~~(consider transesophageal echocardiography if echo windows do not allow for sufficient heart function assessment)~~
~~10~~. 5. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final organ acceptance

~~For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.~~

~~The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.~~

2.11.D Required Information for Deceased Lung Donors

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

~~1. Height~~
~~2. Weight~~
~~3. Vital signs, including blood pressure, heart rate, and temperature~~
~~4. History of medical treatment in hospital including vasopressors and hydration~~
~~5. Smoking history~~

~~6. Cardiopulmonary, social, and drug activity histories~~
~~7.~~1. Arterial blood gases and ventilator settings on 5 cm/H_20/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2, within 2 hours prior to the offer
~~8.~~2. Bronchoscopy results, if performed
~~9.~~3. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
4. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance
~~10. Details of any documented cardiac arrest or hypotensive episodes~~
~~11.~~5. Sputum gram stain, with description of sputum
~~12. Electrocardiogram~~
~~13. Echocardiogram, if the OPO has the facilities~~
~~14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance~~

~~If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.5.B: Time Limit for Acceptance* are maintained.~~

~~For lung deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.~~

~~The lung recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite OPO donor coordinator in order to obtain current information about the deceased donor's physiology.~~

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

~~1. Donor name~~
~~2. Donor ID~~
~~3. Ethnicity~~
~~4. Weight~~
~~5. Date of admission for the current hospitalization~~
~~6. Alcohol use (if known)~~
~~7. Current history of abdominal injuries and operations including pancreatic trauma~~
~~8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria~~
~~9. Current medication and transfusion history~~
~~10. Pertinent past medical or social history including pancreatitis~~
~~11.~~ 1. ~~Familial~~ Family history of diabetes (including Type 1 and Type 2)
2. Hemoglobin A1C, if performed
3. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
~~12.~~ 4. Insulin protocol
~~13. Indications of sepsis~~
~~14.~~ 5. Serum amylase
~~15.~~ 6. Serum lipase

16. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers

2.12 Requested Deceased Donor Information

2.12.A Kidney

With each kidney offer, the host OPO should provide the receiving transplant program with the following biopsy information for kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85%, and for all other kidneys at the request of the accepting surgeon:

1. Wedge biopsy with the sample measuring approximately 10 mm (length) by 5 mm (width) and 5 mm (depth)
2. A sample that captures a minimum of 25 glomeruli
3. A frozen or fixed section slide, or the biopsy material, may accompany the kidney.

2.12.B Heart

With each heart offer, the host OPO should provide *all* of the following information to the receiving transplant hospital:

1. Coronary angiography (for male donors over 40 years old or female donors over 45 years old)
2. Central venous pressure (CVP) or Swan Ganz instrumentation
3. Cardiology consult
4. Cardiac enzymes, including creatinine phosphokinase (CPK) isoenzymes

A transplant hospital may request a heart catheterization of the deceased donor where the donor's medical or social history reveals at least *one* of the following past medical histories:

- Male over 40 years old or female over 45 years old
- Segmental wall motion abnormality on echo
- Troponin elevation
- History of chest pain
- Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction
- History of *two or more* of the following:
  - Cocaine or amphetamine use
  - Diabetes
  - Hyperlipidemia
  - Hypertension
  - Intra-cerebral bleeding
  - Significant smoking
  - Strong family history of coronary artery disease

2.12.C Lung

The host OPO should provide *all* of the following information to the receiving transplant hospital:

1. Measurement of chest circumference at the level of nipples
2. Measurement by chest x-ray vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm
3. Mycology sputum smear
4. Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant hospital

5.6 Receiving and Accepting Organ Offers

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

A transplant hospital must access deceased donor information in the match system within ~~one hour~~ 30 minutes of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused~~.~~ and it is permissible for the host OPO to enter an offer refusal.

Transplant hospitals must either ~~accept or refuse the organ~~ submit to the OPTN Contractor a provisional yes or an organ offer refusal within ~~one hour~~ 30 minutes of accessing the deceased donor information ~~required for an organ according to *Policy 2.3: Evaluating and Screening Potential Deceased Donors*~~. If the transplant hospital does not ~~respond within this time~~ submit a provisional yes or an organ offer refusal within 30 minutes, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.

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, then the transplant hospital must respond to the host OPO within one hour of receiving notification of the primary offer with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

If the transplant hospital does not respond within one hour, it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to VCA transplants.

5.6.C Organ Offer Acceptance Limit

For any one candidate, the transplant hospital can only have two organ offer acceptances for each organ type. The host OPO must immediately report the transplant hospital acceptances to the OPTN Contractor.

5.6.~~C~~D Effect of Acceptance

When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.