At-a-Glance

Proposal to Allow Collective Patient and Wait Time Transfers

- **Affected/Proposed Policies and Bylaws:** Policy 3.6.C (Waiting Time Transfers); Policy 3.8 (New: Collective Patient Transfers); Bylaws K.6 (Transferred Candidates Waiting Time)

- **Operations and Safety Committee**

  This proposal provides a process to transfer patients and their wait time collectively when a transplant program stops performing organ transplants due to one of the following:

  - long-term inactivity
  - withdrawal of membership
  - termination of membership

  Current policy and bylaws outline a process by which a registered individual can transfer primary waiting time. Processing large groups of patients who must transfer when a program stops performing transplants for an extended period is currently challenging. These situations could be handled safely and efficiently through a collective transfer process. This proposal outlines requirements to allow the OPTN to transfer patients collectively.

- **Affected Groups**
  Transplant Administrators
  Transplant Coordinators
  Transplant Program Directors
  Organ Candidates

- **Number of Potential Candidates Affected**
  All listed transplant candidates may be affected if their transplant program enters into long-term inactivity, withdraws OPTN membership, or experiences OPTN membership termination. From 2011-2013, 45 programs were withdrawn, with a total of 1,524 candidates on their wait lists within the 180 days prior to program closure.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal supports the following strategic plan goals:

  1. Promote transplant patient safety
  2. Promote efficient management of the OPTN

  The proposal promotes transplant patient safety, as all information will be transferred electronically reducing possibilities for data entry or transcription errors if records are re-entered or manually adjusted. The proposal promotes efficient management of the OPTN by converting an individual process to a collective process, reducing opportunity for lost paperwork and transfer processing time, and restoring opportunity for transplant in a timely manner.

- **Specific Requests for Comment**
    1. Should a deadline be proposed to complete full evaluations following a collective transfer?
    2. Should post-transfer reporting be done every 90 days until the post-transfer evaluation plan is complete?
    3. Should a new post-transfer evaluation plan be developed if circumstances change?
    4. What are expectations about the receiving transplant program communicating active versus inactive status to candidates?

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Operations and Safety Committee

Public Comment Response Period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

This proposal provides a process to transfer patients and their wait time collectively when a transplant program stops performing organ transplants due to a status change to one of the following:

- long-term inactivity
- withdrawal of membership
- termination of membership

Current policy and bylaws outline a process by which a registered individual can transfer primary waiting time. Processing large groups of patients who must transfer when a program stops performing transplants for an extended period is currently challenging. These situations could be handled safely and efficiently through a collective transfer process. This proposal outlines requirements to allow the OPTN to transfer patients collectively.

Background and Significance of the Proposal:

Current OPTN Policy 3.6.C (Waiting Time Transfers) provides a specific mechanism using the individual Wait Time Transfer Form when a transplant candidate wishes to transfer primary waiting time from one transplant hospital to another. These forms are completed by either transplant hospital and sent to the OPTN Contractor. The OPTN Contractor processes these forms manually. Each transfer takes up to 30 minutes to complete. When a transplant hospital enters long-term inactivity or closes, significant numbers of patients might need to be transferred within a short time frame. Using the individual process to complete this task creates a burden on transplant programs and a data entry backlog with potential for delayed entry, missing patient forms, and delayed transplant opportunities.

This proposal would create an official process where the closing center and accepting center(s) would sign an agreement and provide the OPTN with a list(s) of patients to be transferred. The process would keep all current required patient notifications in place and would not bypass providing transfer choices.

The OPTN Contractor will:

- Review the patient transfer list(s)
- Provide notification to the hospitals once the collective transfer(s) has been completed
- Provide the accepting hospital with a list of patients transferred

The receiving program will:

- Assume management of the transferred patients without any record modifications
- Assume other applicable patient notification and regulatory requirements.
- Designate the appropriate patient status according to their protocols and selection criteria.

The proposal would authorize the OPTN to complete collective transfers if a transplant program no longer qualifies as a designated transplant program prior to fulfilling the outlined requirements and the accepting transplant program requests completion of the transfer.

This proposal was developed under leadership of the Operations and Safety Committee. The workgroup addressing this issue included representatives from the Transplant Administrators, Transplant Coordinators, and Patient Affairs Committees. In addition, UNOS staff, which provide assistance during program closures, participated in the group. This work group also developed a resource tool kit to help answer common questions, share effective practices, and highlight current requirements when transplant programs inactivate long-term or close.

Alternatives considered would be to 1) continue using the individual wait time transfer process in large volume situations or 2) to transfer patients collectively but place them in an inactive status until evaluation is completed at the accepting transplant program. The current individual wait time process will continue to be used if this proposal is not approved. Placing a patient into an inactive status for transfer purposes was debated but not considered an appropriate function of the OPTN. The proposal does place responsibility to manage the patient's status from the effective date of transfer with the accepting program. All data and records in UNet [SM] from the closing transplant program will transfer without modification to the accepting program. Accepting programs would need to consider placing the candidate into an inactive status if an evaluation at their program is needed but not completed.

The proposal's strength includes providing a structure that can be tailored to the unique circumstances of a program's long-term inactivation or closure. The closing program must still provide choice as currently required and obtain patient consent. It provides OPTN review as well as requires a signed agreement among the hospitals with specified responsibilities. The process also authorizes the OPTN to facilitate transfers in sudden closures.

Accepting hospitals will be required to submit and implement a post-transfer evaluation plan to the OPTN to describe expected dates and a process to manage the newly transferred patients. This is both a strength and weakness of the proposal. The strength is that this allows hospitals to develop plans tailored to their specific needs and situations. The weakness is that there are no uniform standards and timeliness of patient evaluations may vary. Currently no plan is required and some may view this as burdensome. The committee will follow these plans if this proposal is implemented.

Weaknesses of the proposal include that the accepting transplant program will assume responsibility immediately upon transfer to manage a potentially large number of new patients. The proposal, however, does require that closing and accepting programs agree upon a date of transfer. This will allow accepting programs to identify and increase staff resources needed to efficiently facilitate the transfer and evaluations prior to the agreed upon transfer date.

Supporting Evidence/Modeling:

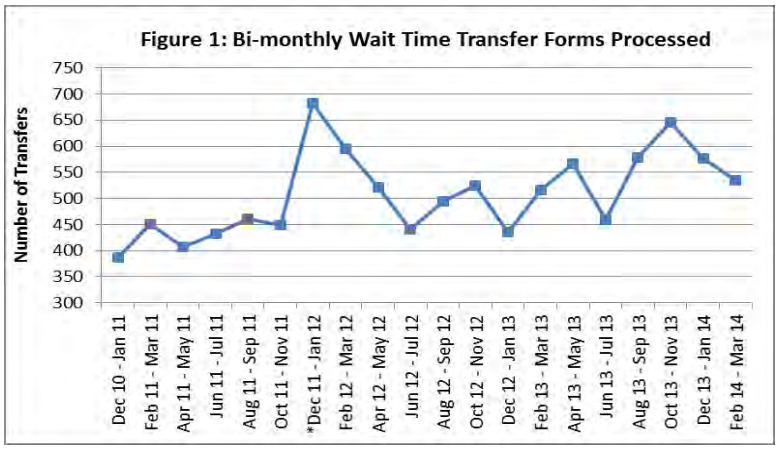
Transplant program closures can have a major impact on transplant prospects for patients listed with the closing program. In one instance, a hospital and all its transplant programs closed in December 2011 leaving over 400 candidates without access to services. Subsequently, another hospital started transplant services in early 2012 to serve the area which otherwise had no providers without requiring travel to the U.S. mainland. To restore and expedite their opportunity for transplant, a request was made to process these candidates as a group rather than individually. Consents were obtained and documented by the active transplant hospital. A list of these patients was provided to the OPTN. An information technology solution to transfer these patients collectively was employed substituting the new program's 8-character OPTN center code (e.g., ABCD-TX1) for the closed program. This effectively and efficiently transferred the entire candidate record, including waiting time. The OPTN Executive Committee approved waiving a second registration fee at the new program. This situation required special considerations and highlighted the need to address these types of circumstances in policy. The Committee's proposal would codify the authority and requirements to perform collective transfers.

Between January 2011 and December 31, 2013, 37 transplant hospitals withdrew designated OPTN program status (closed) for at least one program (45 total programs withdrawn). There were 1524 waitlisted candidates at these 45 programs within the 180 days prior to program closure. Over the three-year period from 2011-2013, this averaged to approximately 15 programs withdrawn from 12 transplant hospitals per year.

Individual transfers take approximately 30 minutes to process manually. The previously mentioned example would have required approximately 200 hours of OPTN staff time to process individually. It was estimated that an individual process for this situation would have taken one to two months to complete. The downside to this would have been taking needed resources away from routine transfers and potentially reducing transplant opportunities due to a slower and more inefficient process. By relying solely on signed individual forms, it might be possible that some patients would be missed or further delayed into being transferred to the new program.

Between December 2010 and March 2014, 10,158 individual Wait Time Transfer Forms were processed by the OPTN Contractor, averaging 254 individual forms per month (Figure 1). Transfers resulting from long-term inactivation or closures present an opportunity to overwhelm

Figure 1: Bi-monthly Wait Time Transfer Forms Processed



*Data Source: Organ Center, UNOS. *410 collectively transferred candidates not included.*

the system designed for individual transfers. Furthermore, the average transplant hospital in May 2014 had 496 total candidates. Nearly half (49%) of transplant hospitals have more than 300 candidates and 40 transplant hospitals have more than 1,000 candidates. Allowing use of an automated, collective transfer function would more efficiently transfer patients faced with a transplant program or hospital closure and minimize disruption to the Organ Center's current individual transfer process.

Expected Impact on Living Donors or Living Donation:

Living donation candidates registered in UNet [SM] who indicate a willingness to accept deceased donor organs could be impacted. The impact could be a more efficient transfer to the receiving transplant hospital and ability to receive deceased donor organ offers.

Expected Impact on Specific Patient Populations:

This proposal will not have a disproportionate impact on any specific patient population other than those populations who are patients at a closing or long-term inactivating transplant program.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal supports the following OPTN Strategic Plan Goals:

- Promote transplant patient safety
- Promote efficient management of the OPTN

The proposal promotes transplant patient safety, as all information will be transferred electronically reducing possibilities for data entry or transcription errors if records are re-entered or manually adjusted. The proposal promotes efficient management of the OPTN by converting an individual process to a collective process, reducing opportunity for lost paperwork and transfer processing time, and restoring opportunity for transplant in a timely manner.

Plan for Evaluating the Proposal:

The primary goal of this proposal is to ensure that patients from closing transplant programs have the opportunity to transfer their care to active transplant programs in a timely manner.

In order to track the effectiveness of the proposed bylaw changes, the Committee will review data regarding the frequency of collective waitlist transfer requests, the number of patients collectively transferred, and the processing time for the collective transfers versus comparable time for individual transfers.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect September 1, 2015.

Communication and Education Plan:

This proposal will affect only transplant hospitals and their patients for programs entering into long-term inactivity, withdrawal, or termination. The customary policy notice will be used for

communicating changes to the community. UNOS staff will be available to answer individual questions.

Compliance Monitoring:

The OPTN Contractor will review the written collective patient transfer agreement and plan for completeness and suitability. A written progress report from the accepting transplant program must be submitted to staff no later than 90 days from the actual patient transfer date. Noncompliance with submission of this report will result in referral to the Membership and Professional Standards Committee (MPSC). After receipt of the 90 day report staff will revisit the submitted plan to assess if it is accomplishing the desired safe and efficient evaluation of transferred patients. If a staff review of the plan finds concerns, then a referral can be made to the MPSC for its consideration regarding potential nonfulfillment with the original plan.

Policy or Bylaw Proposal:

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

3.6.C Individual Waiting Time Transfers

A candidate may transfer primary waiting time from one transplant hospital to another if it meets the requirements below:

1. The candidate must be registered at both transplant hospitals.
2. One of the transplant hospitals must submit a Wait Time Transfer Form to the OPTN Contractor.
3. The OPTN Contractor will transfer the primary qualifying date and waiting time accrued from the earlier transplant hospital to the new transplant hospital.
4. If the candidate chooses not to have multiple registrations, the OPTN Contractor will remove the candidate from the waiting list of the earlier transplant hospital.

If the candidate chooses to have multiple registrations, the OPTN Contractor will exchange the primary waiting time from the transplant hospital that had the primary qualifying date and waiting time with the more recent transplant hospital.

The OPTN Contractor will send a notice of the primary waiting time transfer to each of the transplant hospitals involved.

3.8 Collective Patient Transfers

The OPTN Contractor may collectively transfer patients from transplant programs with a status of long-term inactive, withdrawal, or termination, to one or more transplant programs according to *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of the OPTN Bylaws. Candidates transferred as part of a collective transfer will retain waiting time according to *Appendix K.6: Transferred Candidates Waiting Time.*

3.~~8~~9 Removing Candidates from the Waiting List

OPTN Bylaws:

K.6 Transferred Candidates Waiting Time

To ensure equity in waiting times and ease the transfer of candidates from the waiting list, the candidates at programs that voluntarily inactivate, withdraw or lose designated transplant program status will:

1. Retain existing waiting time.
2. Continue to accrue waiting time according to their status on the waiting list at the time of the program's inactivation, withdrawal, or termination of designated transplant program status.

This total accrued waiting time can be transferred to the candidate's credit when the candidate is listed with a new transplant program.

The OPTN Contractor may collectively transfer patients from a transplant program, with a status of long-term inactive, withdrawal, or termination, to one or more active transplant programs.

The transferring transplant program must complete *all* of the following before a collective transfer:

1. All required patient notifications according to *Section K.3 Long-term Inactive Transplant Program Status* or *Section K.4 Withdrawal or Termination of Designated Transplant Program Status*.

2. A written agreement with each accepting transplant program that includes *all* of the following:
   a. Request for collective transfer of candidates' waiting times
   b. List of patient names and identifiers to be transferred
   c. Mutually agreed upon transfer date
   d. Assurance of notification and consent according to *Section K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal*
   e. Acknowledgement that all patient information and records available to the OPTN Contractor will be transferred without modification
   f. Acknowledgement that the transplant program accepting the patients accepts responsibility for patient notification and management according to all applicable OPTN Policies and Bylaws

Each accepting transplant program must develop and implement a plan that includes *all* of the following:
1. Procedure for immediate review and designation of appropriate candidate waiting list status upon completion of the collective transfer
2. Expected date for completing full evaluations and subsequent waiting list status adjustments on collective transfer candidates according to the accepting programs' selection and listing protocol

Upon receipt of the written agreement and plan, the OPTN Contractor will review the information and provide an expected collective transfer completion date to all the transplant programs involved. After the collective transfer process has been completed, the OPTN Contractor will provide written notification to the transplant programs.

The accepting hospital must submit a progress report containing a status update on each collective transfer candidate to the OPTN Contractor within 90 days after the collective transfer is completed.

If the transferring transplant program no longer qualifies as a designated transplant program and does not complete the requirements according to *Appendix K*, the OPTN Contractor may approve and complete a collective transfer of candidates' registrations and waiting times if the accepting transplant program requests in writing to complete the transfer.