

At-a-Glance

Proposal to Clarify Definition of Organ Transplant and Transplant Date

- **Affected/Proposed Policy:** Policy 1.2: Definitions

- **Policy Oversight Committee (POC)**

UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what should be reported as the transplant date, especially in regards to meeting reporting requirements in UNetSM. Members report that there is a disconnect in current definitions and actual clinical practices, and these proposed definitions will help bridge the disconnect and clarify the policy requirements.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
Transplant Program Directors
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Compliance with OPTN Strategic Plan and Final Rule**

By clarifying the definition for organ transplant and the start and end of transplant, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. This proposal also supports the specific strategy to improve readability of OPTN rules and requirements. Since it will also enhance reporting of transplant procedures and increase accuracy of reporting, the proposed improvements to policy language could increase patient safety.

- **Specific Requests for Comment**

The Committee invites comment on whether the proposed language clarifies transplant date as well as the start and end of the transplant procedure for reporting and removal of candidates from the waiting list. Additional input on whether this proposal supports current clinical practices is welcome.

Proposal to Clarify Definition of Organ Transplant and Transplant Date

Affected/Proposed Policy: Policy 1.2: Definitions

Policy Oversight Committee (POC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what should be reported as the transplant date, especially in regards to meeting reporting requirements in UNetSM. Members report that there is a disconnect between the current definitions and actual clinical practices, and these proposed definitions will help bridge the disconnect and clarify the policy requirements.

Background and Significance of the Proposal:

UNOS staff receives numerous questions about how to report the start and end date of transplant. This proposal aims to clarify this so that OPTN members can effectively meet reporting requirements in UNetSM.

- **Collaboration:** UNOS staff collaborated to identify the problem with the current definitions of organ transplant and transplant date as reported by our members. A major concern of staff and POC was to ensure that we did not unknowingly affect other policies or reporting requirements when we changed these definitions. Therefore a workgroup of the POC discussed all of the situations in policy where transplant dates are relevant. The POC, which is made up with representatives from all the OPTN/UNOS Committees, reviewed and approved the final policy proposal.
- **Alternatives considered:** The Committee explored the idea of combining the two separate definitions, if possible, but decided that both were required since having a separate definition for transplant date clarifies the reporting requirements. The two definitions ensure that data reported to the OPTN reflect what actually happens in a single-organ or a multi-organ transplant. The definition for organ transplant focuses on both when the transplant begins (at anastomosis of *that* organ), and an organ transplant is complete (when the cavity is closed and final stitch or staple applied or when the recipient leaves the OR). The definition for *transplant date* requires that the transplant date for an organ would be determined by the start of anastomosis for each organ, so you could have a multi-organ transplant occur on two different days.
- **Description of intended and unintended consequences:** The Committee and UNOS staff carefully considered whether changing these definitions would affect other policies in an unintended way, and they could find no other areas in current policy that would be affected by the change.

Supporting Evidence and/or Modeling:

For reporting date of transplant and the subsequent removal of candidates from the waiting list, members often have questions about the exact date to report for the start of a transplant

procedure and the end of a transplant procedure. A majority of the questions focus on how current clinical practice is sometimes out of sync with the current definitions in OPTN Policy.

The following two scenarios present the most common concerns and questions:

1. A candidate received a liver transplant but the organ was larger than expected, so the surgical team did not immediately close the abdomen. The patient is removed from the operating room and subsequently dies three days later. Per current policy, the transplant was not complete until the abdominal cavity was closed; therefore, the candidate would remain on the waiting list for those intervening three days until removed using removal code 21 – *died during the transplant procedure*.

POC members discussed a common practice for candidates to be packed with sterile mesh in order to allow for post-transplant intervention and removed from the operating room. Once the immediate concern has passed, the candidate returns to the operating room for placement of the final stitch. By clinical standards, POC members agreed that the transplant concluded when the candidate originally left the operating room, but the policy requirement was not met due to the absence of the final stitch.

These cases show the need for clarification of when a transplant procedure officially ends, and the addition of language to provide for the end of transplant once the candidate leaves the operating room, regardless of whether or not the final stitch is completed, will clarify this issue.

2. In the case of a multi-organ transplant, a recipient leaves the operating room after receiving the first organ transplant and then returns to the operating room on the next day to receive a second organ from the same donor. Per current policy, the date of transplant for the second organ is recorded as the date of the first organ's anastomosis, which occurred more than 24 hours prior.

The evolving clinical practice of a time lapse between individual organ transplants during a multi-organ procedure is not addressed in current policy. Current policy states: *For a multi-organ transplant procedure, the transplant date for each organ is determined by the transplant date of the first organ transplanted*. In order to comply with the requirement to remove a patient from the waiting list within 24 hours of transplant, the transplant hospital would need to remove a patient from an organ's waiting list prior to the patient receiving that organ, since the clock starts to tick when the first organ is transplanted, regardless of the organs that follow.

A subcommittee of the POC was convened to discuss these issues and recurring questions. They concluded that the current definitions do not provide a reporting mechanism for a transplant hospital to accurately report the events described above. This proposal offers revisions to policy that:

- Maintain the current reporting elements while capturing existing clinical practice
- Ensure data reported to the OPTN reflect what actually happens in a single-organ or multi-organ transplant

Expected Impact on Living Donors or Living Donation:

This proposed policy change will change the required reporting date of transplant for living donors.

Expected Impact on Specific Patient Populations:

This proposed policy change will not directly impact any specific patient population.

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

By clarifying the definition for organ transplant and the start and end of transplant, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. This proposal also supports the specific strategy to improve readability of OPTN rules and requirements. Since it will also enhance reporting of transplant procedures and increase accuracy of reporting, the proposed improvements to policy language could increase patient safety.

Plan for Evaluating the Proposal:

The Committee will continue to communicate with staff to determine if members continue to have questions and concerns when reporting the transplant date to the OPTN and complying with timely removal of candidates from the organ waiting list.

Additional Data Collection:

There is no additional data collection required as a result of this policy change. The proposal will help support more accurate reporting of transplant date and may help members comply with candidate removal from the waiting list requirements.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June, 2015 and, if approved, the clarified definitions will become effective pending programming.

Communication and Education Plan:

This proposal may require that members change how they currently report transplant date and remove candidates from the waiting list. The following Communication & Education Activities will help notify members of the clarified definitions:

- Policy notice
- Online article
- Presentation at Regional Meetings

Compliance Monitoring:

Members will be expected to accurately report data based on the proposed language. Although the proposed language will not change the fields routinely monitored, members will be expected to apply the new definitions of organ transplant and transplant date when reporting in UNetSM. Any data entered in UNetSM may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Proposal:

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

1.2: Definitions

Organ transplant

Organ transplants include solid organ transplants and islet infusions. An organ transplant begins at the start of ~~once any initiation of organ~~ anastomosis ~~has taken place during the intended transplant~~ or the start of an islet cell infusion. An organ transplant procedure is complete when ~~either any of the following~~ occurs:

- The chest or abdominal cavity is closed and the final skin stitch or staple is applied.
- The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.
- The islet cell infusion is complete.

Transplant date

Determined by the start of the organ anastomosis during transplant or the start of the islet infusion. ~~beginning of organ anastomosis. For a multi-organ transplant procedure, the transplant date for each organ is determined by the transplant date of the first organ transplanted.~~