OPTN Patient Affairs Committee

Patient Awareness of Listing Status (PALS) Subcommittee
Meeting Summary
September 17, 2024
Conference Call

Garrett W. Erdle, Subcommittee Chair

Introduction

The Patient Affairs Committee's Patient Awareness of Listing Status (PALS) Subcommittee met via Teams teleconference on September 17, 2024, to discuss the following agenda items:

1. Welcome and Announcements
2. Recap/Comments from PAC In-Person Discussion, September 10, 2024
3. Next Steps in Advancing Proposed Project

The following is a summary of the Subcommittee's discussion.

1. Welcome and Announcements

The Subcommittee Chair welcomed Subcommittee members and thanked them for their ongoing participation.

2. Recap/Comment from PAC In-Person Meeting Discussion, September 10, 2024

The Subcommittee Chair provided a recap of discussion from the previous week's meeting in Detroit.

No decisions were made.

Summary of discussion:

The Subcommittee Chair provided highlights of the brief PALS overview offered during the PAC's in-person meeting. Informal discussion with Minority Affairs, Ethics, Living Donor, and Transplant Coordinators Committees regarding this proposed effort was highlighted, including verbal support pending additional details. OPTN Contractor staff noted that careful consideration will be needed regarding data security related to sharing protected health information through a phone application. The OPTN Contractor staff had previously noted that assigning this responsibility to the transplant centers (with many already having these types of protections in place for electronic medical records) with a policy requirement is a potential pathway for consideration. The Subcommittee Chair stated that he wanted to avoid human dependencies here and saw better uses for coordinator time than to focus on this administrative ask of transplant programs. There was unanimous support from the full Committee to move forward with this proposed project effort.

3. Next Steps in Advancing Proposed PALS Project

No decisions were made.

Summary of presentation:

The Subcommittee briefly reviewed the desired solution and whether it should it be a phone application, a hospital's patient portal (with application programming interface (API) from the OPTN Computer System to communicate information from the system), or policy requiring communication of inactive status that would leave the technical solution to each transplant center to determine.

The pros and cons of a policy solution were reviewed. When the Subcommittee drafted a framework, they saw this as a framework to help avoid mislabeling of a candidate as inactive and a way to encourage the candidate population to take an active role in their transplant care. This was also seen as an opportunity to increase trust in the transplant process by improving transparency. In addition, the phone application was seen as a potential vehicle to provide future functionality to benefit patients beyond only verification of waitlist status to candidates.

Organ non-use recognized as an ongoing concern for the transplant community. The Subcommittee Chair speculated that this effort may be able to reduce the number of discards if more candidates were active and receiving offers on the waitlist.

The proposed phone application was recognized by the Subcommittee Chair as something not done before within the OPTN. This project would pull data from the OPTN system and make it available to the patient population.

The Subcommittee Chair noted that this idea is not a new one, with the full Committee considering this exact effort several years ago. A past PAC member reached out to the Subcommittee Chair in March 2024 to determine whether any advances have been made in this area. This was noted as reflecting the desire from patients to want access to this information.

The Subcommittee Chair had reached out to external contacts regarding the technological component of this proposed idea. A flow chart, circulated to Subcommittee members prior to this call, was presented as a potential way of communicating OPTN data to phone application solution. After reviewing the pros and cons of potential policy and phone application solutions, the Subcommittee Chair sought feedback from Subcommittee members and OPTN Contractor Staff.

Summary of discussion:

One Subcommittee member sought clarification on the requirements related to Policy 3.5 *Patient Notification*. After talking with clinicians at a regional meeting, he noted that there was confusion on whether this was already a requirement in policy to notify patients regarding inactive status. OPTN Contractor staff shared this relevant OPTN Policy[1] and CMS Condition of Participation § 482.94[2] related to this comment, confirming that there is no specific requirement in place for notification of inactive status. The only current requirements for notification are upon listing, if evaluated and not listed, or if

[1] OPTN Policy. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf. Accessed 10/2/2024
[2] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E/subject-group-ECFRc4be2badf376a95/section-482.94. Accessed 10/2/2024

removed from the waitlist for reasons other than transplant or death. The Subcommittee member sees this confusion as a hurdle requiring communication to transplant centers. He noted that in his conversations, center staff stated that they communicate with patients about this (though he was not sure whether this was specific to inactive status or delisting). OPTN Contractor staff noted that though it is believed that most candidates are aware of their current status, a number of compelling anecdotal stories have been shared within the committee that this was supported as an important effort for the PAC.

A Subcommittee member questioned why this is not already specifically outlined in policy if the thought is that most candidates are aware of status. She was troubled that this would not be a basic expectation. OPTN Contractor staff and the HRSA representative noted that anyone in the donation or transplantation community can bring up policy recommendations or concerns to address, recognizing that this has been discussed for several years by the Committee but there has been no interest in proposing policy in this area to date. The OPTN Contractor does not propose policies or projects, but rather the overall donation and transplantation community does. If this is something that the Committee wishes to explore, it should be proposed to the OPTN Policy Oversight Committee (POC) for project consideration. To date, the Subcommittee and Committee have focused on a technological solution rather than a policy requirement, which somewhat deviates from the traditional POC policy development pathway. In that case, the OPTN Board of Directors might be asked to consider this project as a large non-policy effort that is anticipated to be resource intensive for IT development. All projects must be evaluated against the full complement of projects worked on and/or proposed by other committees. The PAC Co-Chair sits on the POC as well and may be able to provide insight on the policy development process and the new policy projects which were recently approved. Two of these were relatively large projects in cost and effort.

The issue of candidates listing at more than one center was also briefly discussed, noting that candidate information will need to be specific to the center. It will be important to include language that clearly notes that any questions related to listing status or how to return to active status should be directed to the listing transplant center and not the OPTN. A Subcommittee member shared his family's experience being listed at two separate centers within the same region. One clearly notified them regarding the candidate's inactive status. The second shared no communication regarding placing a family member in an inactive status. The Subcommittee suggested that the candidate or their caregiver be able to enter a numeric patient ID to gain access either through a phone application or to a voice recording that would clearly indicate that the patient identified by that ID number is active or inactive on the waitlist. If multiple listings are involved, the patient might have separate ID numbers for each that could be provided by the transplant program at time of listing.

OPTN Contractor staff noted that there will be no means to enforce or monitor patient usage of the app. The Subcommittee Chair noted that the goal is to make the information available to patients, increasing transparency of the system. This access will allow them the ability to monitor their status and provide some peace of mind to those awaiting transplant. The Chair emphasized that, while this approach will be novel for the OPTN, it is used by other organizations and business to convey information.

The Subcommittee Chair asked for OPTN Contractor IT staff to provide feedback on the flow chart developed outside of the OPTN, asking if there were technical barriers or issues that need to be tackled. OPTN Contractor staff acknowledged that they had briefly reviewed the flow chart but noted that it would be beneficial to have the person who created the chart walk through it and explain the differences between the options. The overall impression is that the chart focuses on how to get information out of the waitlist regarding patient status, but OPTN Contractor staff noted that the flow chart does not recognize the security issues of requiring the system to not only release the information

to the candidate but also to an authorized representative. To release this protected health information, user identity will need to be verified according to the requirements HRSA System of Records Notice 09-15-0055 (Records Access Procedures).[3] Additional OPTN resources will be needed to determine the path forward for meeting these requirements when providing data through the proposed phone application. To do that, project approval by the POC or OPTN Board of Directors is needed before OPTN resources can be committed and utilized. Discussion and research will be required with IT, Legal, and HRSA to understand and agree upon the requirements here to ensure that data is shared appropriately.

Subcommittee members and OPTN Contract Staff offered real-world examples of sharing sensitive information via phone applications. Signing up for patient portals or seeking a report to verify your credit score were offered as examples of the types of verifications that will be needed. OPTN Contractor Staff noted that once the phone application was consulted by a candidate or their caregiver, they would still need to contact their transplant program for further information on why they were set to an inactive status and what needs to be done to move back to active status. Staff noted that it will be important to provide clear messaging here, so users understand that the OPTN does not have this information and cannot assist them with these questions.

The Subcommittee recognized the challenges in developing a novel approach to patient communication but recognized that this was manageable in banking and pharmacy companies who also share sensitive information via apps.

A Subcommittee member shared that he had asked centers how the inactive code was used to better understand this issue. He was told that it is often used in short bursts of time until all criteria are met, and an individual is ready to receive organ offers. He noted that it is sometimes patient driven for vacations or inaccessibility. There are also long term uses for inactive status such as during periods of illness where transplant would not be appropriate. The member offered that, in considering the three options (policy, policy plus APIs to help centers communicate the information through their electronic medical records or patient portals, or the development of a phone application), he suggested the policy and API solution. He noted that this would make transplant programs that are not making these notifications responsible for doing so. He did question whether centers were providing notifications of the use of short term or short bursts of inactive status, noting that with 40,000+ people in an inactive status there is no way that centers are equitably contacting all of these people in real time. As a result, he suggested that a new policy could drive the desired outcome of patient communication while also offering technology to help make this information accessible over time.

[3] System of Record Notice 09-15-0055 | HRSA. Accessed 10/7/2024. Specifically, the SORN provides that, "Individuals may request access to records about them in this system of records by submitting a written access request to the OPTN or SRTR contractor identified in the "System Manager(s)" section of this SORN at the email address provided in that section. The request must contain the individual's full name, address, date of birth, and signature; the name of the applicable transplant center; and a reasonable description of the records sought. To verify the requester's identity, the signature must be notarized or the request must include the requester's written certification that the requester is the individual who the requester claims to be and that the requester understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. The individual may also request an accounting of disclosures that have been made of the records, if any. A parent or guardian who requests access to records about a minor or an individual with diminished capacity must verify his or her relationship to the minor or incompetent individual as well as his/her own identity."

The Subcommittee Chair noted that centralizing this information would take fewer resources and also give the same experience/asset to patients whether they were at smaller or larger programs. The Subcommittee recognized the variability in program resources, but the policy would at least enforce the requirement that the communication should be happening in the short term. One Subcommittee member offered surprise and concern that such basic communication would not be required of transplant programs in caring for the patients.

A question was raised regarding the timeline for reporting inactive status in the OPTN Computer System. OPTN Contractor staff noted that transplant programs add information on patients as they are completing the work up for listing and the system is online 24 hours a day, seven days a week. Once listed, it is up to centers to move the patient in and out of inactive status as needed, recognizing that no offers are made to inactive candidates.

OPTN Contractor staff reinforced the need to take this project forward for approval in order to truly marshal OPTN resources to answer the types of questions that are being generated on this call, noting that the Subcommittee seeking its own external IT feedback on a potential solution is atypical of projects and the policy development process. Subcommittee leadership reinforced its thoughts that it has no interest in advancing an effort that is not wanted and suggested that it is important to understand the challenges here and be prepared to answer them.

A guest on the call recognized that this project was first pursued by the Transplant Coordinators Committee with a requirement that written letters go to candidates at inactive status for a specific number of days. He appreciated that the current Subcommittee recognizes the challenges and barriers of the original proposal, and the use of technology to hopefully overcome some of these barriers. He suggested that engagement or partnership with the Transplant Coordinators Committee will be valuable here and reiterated the importance of seeking buy in and resource approval at the Board level to effectively advance the effort. He is happy to see this effort get traction, recognizing the potential outcomes of being left at inactive status without knowledge of it.

Another participant noted that informal polling at a recent meeting of transplant coordinators reflected that all centers notify their patients of inactive status, lending support to the idea that many believe this is already a requirement by the OPTN and/or CMS. Some do this through their EMR system electronically, others do it by letter or through a phone call that is documented in the candidate's medical record.

The Chair thanked everyone for their support for this effort and noted a desire to complete it for patients and be cost effective in developing the solution. He hypothesized that providing candidates with this knowledge and transparency will encourage them to be more proactive, and that this may also lead to reduced non-use of organs.

Next Steps:

OPTN Contractor Staff will schedule a standing call for this group to continue its work.

OPTN Contractor Staff will explore a path forward for project approval with HRSA and the OPTN Board

Upcoming Meetings

October 8, 2024

November 12, 2024

December 10, 2024

January 14, 2025

February 11, 2025

March 11, 2025

April 8, 2025

May 13, 2025

Attendance

- **Committee Members**
  - Garrett Erdle, Chair
  - Lorrinda Gray-Davis
  - Michael Brown
  - Justin Wilkerson
  - Jenny Templeton
- **HRSA Representatives**
  - Robert Johnson
  - Mesmin Germain
- **UNOS Staff**
  - Shandie Covington
  - Kaitlin Swanner
  - Desiree Tenenbaum
  - Kimberly Uccellini
  - Rob McTier
  - Laura Schmitt
  - Houlder Hudgins
- **Guests**
  - Joseph Hillenburg
  - Kenny Laferriere