OPTN Patient Affairs Committee
Meeting Summary
March 21, 2023
Conference Call

Garrett Erdle, MBA, Chair
Molly McCarthy, Vice Chair

Introduction

The Patient Affairs Committee (Committee) met via Citrix GoToMeeting teleconference on 03/21/2023 to discuss the following agenda items:

1. Potential project: Inactive status
2. Introduction to Research Department & Role in OPTN Committee Support
3. Discussion

The following is a summary of the Committee's discussions.

1. Potential project: Inactive status

The Committee received a presentation on what a potential project on inactive status could look like, based on the Committee's concern about the volume of candidates inactive on the waitlist, and whether those candidates know that they are inactive. Community members have also suggested that the OPTN update inactive codes to provide more detail on why candidates are inactive. The Committee could consider sponsoring a project that reviews and updates inactive codes and proposes policy changes regarding notifications to patients about inactive status.

The Committee reviewed the current inactive codes:

1. Candidate cannot be contacted
2. Candidate choice
3. Candidate work-up incomplete
4. Insurance issues
5. Medical non-compliance
6. Inappropriate substance use
7. Temporarily too sick
8. Temporarily too well
9. Weight currently inappropriate for transplant
10. Transplanted – removal pending system data correction
11. Inactivation due to [Ventricular Assist Device (VAD)] implantation and/or VAD complication
12. [Transplant] pending
13. Physician/surgeon unavailable
14. Candidate for living donor transplant only
15. [Not in use]
16. COVID-19 precaution

<u>Summary of discussion:</u>

The Chair asked if the proportion of candidates in inactive status has consistently been around 50%, or if that is a more recent occurrence. Staff cited literature reporting that the number of kidney candidates in inactive status increased greatly following a policy change in 2003 that allowed kidney candidates to accrue waiting time while in inactive status, though those candidates are still not eligible for organ offers.[1] Staff said the 50% threshold has been stable since the last time the Committee considered this project. A member said that 50% is a pretty decent proportion since at their transplant program, only one in five candidates is active and the rest are inactive. The member said about 20% of their candidates are preemptively listed and are likely inactive under code #8 ("temporarily too well"). For the other inactive candidates, their program's coordinators and physicians are working on managing what is going on with those patients. The Chair mentioned a previous OPTN project in which something like 80% of the responses were falling into one code and asked if information was available on the breakdown of how the current inactive codes are used. Staff said the Committee could request that data as the first step in the project to see if one code is being used as a default.

A member noted that their transplant program would not list them if they had insurance issues or other issues covered by the inactive codes. The member asked if hospitals or programs by organ type had different criteria for listing. Staff said that transplant programs likely have different practices in terms of whether they prefer to register a candidate and place them in inactive status while resolving issues or wait to register candidates once issues are resolved.

The Committee reviewed the policy requirements for patient notifications. The Chair asked whether transplant programs collect multiple points of contact when a candidate is registered on the list. A member said that their transplant program lists as many contact numbers as are provided.

In part, policy requires transplant hospitals to send a notification within 10 business days when the patient's evaluation for transplant is complete to notify the patient if they will or will not be registered on the waiting list at that time. A member said that some transplant programs are not listing their patients in OPTN Waiting List right away but are keeping them in a "pre-list" status, particularly for patients who expected to have extended times on the waiting list. Once these patients accrue "adequate" waiting time, based on dialysis time, then the transplant program will register them in OPTN Waiting List. The member said the Committee should consider if this practice is fair, legal, and ethical. The member said a lot of money is expended on the pre-transplant work-up and noted that the OPTN captures data on death on the waiting list and death following removal from the waiting list, which may influence why some transplant programs might be keeping some patients in a "pre-list" status, since data on "pre-list" patients is not captured by the OPTN. Staff noted that candidates may not be accruing waiting time if they are not registered on the waiting list and the member clarified that this only applies to candidates on dialysis. The Committee reviewed policy which states that for candidates on dialysis, waiting time is based on "the date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting."[2] Staff also shared that the site survey teams monitor the policy regarding patient notification requirements to make sure that transplant programs are in compliance and as part of this project, staff can check with the site survey teams to see if they have heard about this practice in their site visits. A member noted that site surveys only take place about once every few years.

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[1]Francis L. Delmonico and Maureen A. McBride, "Analysis of the Wait List and Deaths Among Candidates Waiting for a Kidney Transplant," *Transplantation* 86 (2008): 1678-1683, DOI: 10.1097/TP.0b013e31818fe694.

[2]See OPTN *Policy 8.3.A Waiting Time for Candidates Registered at Age 18 Years or Older*, accessed April 4, 2023, https://optn.transplant.hrsa.gov/policies-bylaws/policies/.

The Vice Chair said the "pre-list" approach feels misleading and suggested exploring the financial implications on the insurance side, since transplant evaluation requires a substantial amount of testing. A member said they thought it might be related to money for some centers, but for other centers, they may be overwhelmed by the need for transplant in their area and may keep a proportion of those patients active on the list, and will register additional patients on the list once others have been transplanted. The Chair and Vice Chair expressed concerns about the "pre-list" concept and noted that patients are being impacted even if this practice is an outlier.

A member suggested that transplant programs might also be keeping some candidates inactive until they have more waiting time accrued. The member noted this would only apply to kidney and not to other organs. A member noted that patients would not have visibility on this process because nothing is getting sent out to them. A member said that a transplant program would notify patients of their listing or if they are made inactive but nothing after that. Members discussed that patients must be listed in order to be placed in inactive status, which is distinct from the "pre-list" concept.

The Chair said that it seems like a manual process to have patients in this "pre-list" status. Staff noted that the "pre-list" concept described is not an OPTN process, but it is a good point for the committee to consider as part of this potential project.

The Committee discussed working on a project to update policy requirements for patient notification and update inactive codes to collect more detailed data. The Committee could collaborate with the Transplant Coordinators Committee and the Data Advisory Committee on this project, which would align with the strategic plan goal to improve waitlisted patient outcomes. The Chair said that patients are likely more interested in whether they are on the waiting list than the specific inactive code. Staff said that the Committee can focus on patient notifications, but it may be helpful to look at the data on inactive codes as a starting point to inform the Committee's work one way or another. The Chair agreed with looking at the data but asked for feedback from the Committee. The Vice Chair and other members said they would want to know the inactive code, particularly to help them understand what would need to happen for them to be active on the list. A member said they speak to patients who don't always ask questions while at the transplant center or in the doctor's office, but once they get home, they call the member with questions about why they didn't get listed and what they can do to get listed down the road. The member said that sometimes there can be a bit of a communication gap between the medical team and patients, so it is helpful to have a letter. A member noted that it can be challenging to get someone on the phone at a transplant program to answer questions like this.

Next steps:

The Committee supported reviewing data on inactive codes.

2. Introduction to Research Department & Role in OPTN Committee Support

The Committee received a presentation on the Research department and their role in supporting OPTN committees, including an overview of key roles of the OPTN, OPTN data, the OPTN committee data request process, literature reviews, and examples of how OPTN data requests and available literature can be used to inform policy development work.

Summary of discussion:

The Chair asked if OPTN data inform the predictive analytics tool described in the regional meetings. Staff affirmed that the predictive analytics model is based on OPTN data and offered to follow up with more details. The Vice Chair asked why all this information is not accessible in a self-service model as the data request approach seems cumbersome and costly. Staff said that there is a lot of information

available on the OPTN website[3] and staff are looking at opportunities to make more of the data more readily available.

3. Discussion

The Committee discussed whether to move forward with this project and additional information that would be needed to inform this work.

Summary of discussion:

A member asked if each inactive code is well-defined, noting that lack of standardization could potentially inject some subjectiveness and possibly lead to inequity. Staff said that is a possible opportunity for improvement with the inactive codes because there are not more detailed definitions in the system beyond what was shared with the Committee.

The Vice Chair asked if the Committee could look at frequency of use for each inactive code by organ. Staff affirmed that data can be provided and asked for more feedback on the data the Committee would like to see, for example, if members want data on those who are currently inactive or if they want to look at a wider cohort of patients, for example, every candidate who was inactive in 2022. The Chair said it seems odd that so many patients would be inactive and requested suggestions from staff on how to better understand what is going on. Staff suggested looking at a snapshot in time of currently inactive patients and an ever-waiting cohort of all candidates who were on the waiting list in 2022, as more data would give a sense of trends in how inactive codes are used. The Chair suggested looking at the average time inactive on the waitlist by organ.

A member said that some people can be inactive on list for quite some time, and the past three years in the COVID-19 pandemic have probably resulted in some unusual data. The member said that looking back five years would only leave two years of data pre-COVID and suggested looking back ten years to see the trends and how long some people have been inactive on the waitlist. The Vice Chair agreed with looking back 10 years to capture behavioral trends. The Committee discussed how the data would be provided to members, which would be in a report. A member noted that the overall volume of candidates on the waiting list stays about the same, but candidates are being added to and removed from the list for various reasons all the time, and asked how that would be captured in the data. Staff said they would be capturing frequency of use for the codes but not necessarily the dynamic population over time and asked for more feedback on variables they might be interested in exploring about the population over time.

The Committee discussed options for breaking up the data requests. Staff suggested looking at frequency of use for each inactive code in 2023 and for those ever waiting in 2022 to start and asked if what the Committee would most like to see over the 10-year time frame is how long people are staying inactive. Members said they would like to see how long candidates are staying inactive for each inactive code. The Chair asked if reducing the scope by only looking at kidney would be helpful. Staff said it does not take much longer to look at the inactive codes for all organs but that it is a little more sophisticated to pull the average inactive time by organ so that might take a bit longer to provide to the committee. However, the Committee could opt to limit it to kidney if that makes it more digestible to exclude less commonly transplanted organs like pancreas and vascularized composite allografts. A member asked if the data will be broken down by Region, transplant center, ethnicity, or other factors to see if there is a disparity over a 10-year span. Staff said that is an option. The Chair asked for a small group of committee members to assist in refining the data request as needed. Staff agreed to use the

[3] https://optn.transplant.hrsa.gov/data/.

committee's feedback to put together a proposed plan and follow up with the Committee. The Vice Chair requested more information on what data are publicly available and what data are not as it would be helpful to use members' own data analysis skills to explore a broader dataset. Staff said they would provide data to start and the Committee can always request additional data as needed.

Next steps:

The Committee will continue exploring a potential project on inactive codes and patient notification related to inactive status.

Upcoming Meetings

- April 18, 2023
- Mary 16, 2023
- June 20, 2023

Attendance

- **Committee Members**
  - Garrett Erdle, Chair
  - Molly McCarthy, Vice Chair
  - Anita Patel
  - Calvin Henry
  - Eric Tanis
  - Dana Hong
  - Julie Spear
  - Justin Wilkerson
  - Kenny Laferriere
  - Lorrinda Gray-Davis
  - Sejal Patel
  - Steve Weitzen
- **HRSA Representatives**
  - Arjun Naik
  - Jim Bowman
  - Marilyn Levi
  - Megan Hayden
  - Mesmin Germain
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Alex Carmack
  - Amber Fritz
  - Bridgette Huff
  - Jesse Howell
  - Julia Foutz
  - Kaitlin Swanner
  - Kimberly Uccellini
  - Laure Schmitt
  - Lauren Motley
  - Meghan McDermott
  - Sara Rose Wells