OPTN Operations and Safety Committee
Meeting Summary
September 11, 2024
In Person Meeting

Kim Koontz, MPH, Chair
Steven Potter, MD, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) in person in Richmond, VA and via WebEx teleconference on 09/11/2024 to discuss the following agenda items:

1. OSC Project Update: Re-evaluation of Deceased Donor Testing Requirements
2. Offer Filters Update
3. Update: OPTN Expeditious Task Force
4. Review and Discussion: Kidney Minimum Acceptance Criteria (KiMAC)
5. Public Comment Presentation: Continuous Distribution (CD) of Kidneys Update
6. Wrap Up/Continued Discussion: KiMAC

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

1. OSC Project Update: Re-evaluation of Deceased Donor Testing Requirements

The Committee was provided an update on the Committee's Re-evaluation of Deceased Donor Testing Requirements project.

Summary of discussion:

The Committee Chair suggested consideration for DCD versus (vs) brain dead donors. In thinking about policy, there may need to be something stratified in policy that would allow for flexibility in testing requirements for these different types of donors. The presenter agreed with this and acknowledged that there is a difference and something the Workgroup would consider and discuss.

A member asked that in regard to the data collection component of the project of including a pre/post transfusion field (check box). The member stated that their OPO has a transfusion protocol and that if there is any concern about the donor blood type, they run the donor as AB. The member suggested there being consideration for more than just a checkbox.

A member asked if policies around serology was being looked into as well. Staff stated that this would be related to PHS guidelines. The OPTN policies would need to be consistent with CDC guidelines. It was further explained that there would need to be consultation with the CDC if modifications related to this were to be modified.

A member stated that organ procurement organizations (OPOs) are interpreting that policy differently. The member continued by explaining that the issue is whether serologies need to be resulted or not within 96 hours. There are OPOs that have some of their serologies pending heading into the operating room (OR) so need some guidance. If there is not a need to wait for serologies, that would change what their program would do. Staff stated they would look into this further and would clarify.

Staff clarified that the pre/post transfusion field was a project referral from the OPTN Membership and Professional Standards Committee (MPSC), with the intent to develop a communication pathway between OPOs and transplant programs. A checkbox could just be one way to do it but up to OSC to decide the best way to approach this.

A member stated that a checkbox is a good starting point, but more information is needed. Staff asked the Committee to reach out if more information on the cases that the Membership and Professional Standards Committee (MPSC) reviewed. The Committee was also encouraged to consider the minimum necessary information to achieve the goal given Office of Management and Budget (OMB) implications and wanting to avoid additional administrative burden.

A member suggested consideration for molecular testing for blood type. There have been events where the blood type is not current; there should be consideration if that should be a requirement for A1 vs. A2. Staff commented that the Committee did an ABO subtyping guidance a few years ago which can be reviewed and updated if needed.

There were no additional comments or questions.

Next Steps:

The Committee will continue to be updated on the progress of the work on this project and provide feedback where applicable.

2. Offer Filters Update

The Committee received an update on the Offer Filters project.

Summary of presentation:

The Committee reviewed the following data on offer filter utilization:

- Kidney has highest adoption rate and have had filters the longest
- Filtering ~31% of kidney offers; 10% lung offers; 9% liver offers; 3% heart offers
- For kidney – have seen increases in adoptions following educational offerings, discussions at regional meetings, Offer Acceptance Collaborative, etc.
- Similar early adoption for kidney, lung, liver; heart adopted more slowly
- Percentage (%) of donors filtered per kidney program on average is ~44% (means that program doesn't get notified for that donor)
- Programs notified per donor – was climbing following KAS250 implementation but dropped quite a bit following offer filters implementation

Summary of discussion:

The Committee Vice Chair asked for further clarification of the offer acceptance ratio metric. The presenter explained that bypassed offers are not counted, so for the metric, it is better to have a bypassed offer than to decline an offer. Staff added that there was feedback received that other organs did not have tools to impact their offer acceptance metric so that influenced the decision to proceed with filters for other organs.

The Committee Chair asked if there was a relationship between offer filters and the kidney non-use rate. The presenter commented that this could be looked into more closely. The Committee Chair continued by asking about the data that demonstrated programs that were over filtered and whether or not programs are able to see what was filtered out. Staff confirmed that there are reports available to see what was filtered.

A member noted that if the acceptance rate is good, programs may not feel compelled to use offer filters. The member asked if there was a plan to further educate surgeons. Staff confirmed this point had been brought up before and stated that in holding webinars and collaboratives in the past, it provided the opportunity and was helpful to hear from the surgeons and program directors about their experience using the tools. Attendees reported a feeling of missing out on offers; discussions at the webinars/collaboratives worked to address this concern. It is the hope to have more peer-to-peer education, however, upcoming updates will include additional monitoring.

Another member asked in regard to acceptance rate and filters, if the impact on programs that are using filters was being evaluated. If so, the member asked, how has it improved their offer acceptance rate based on the use of filters? Staff replied that the adjusted rate ratios have not been looked at but there could be a collaboration with SRTR to evaluate this. Staff added that the unadjusted rates were monitored as part of the collaborate which demonstrated better acceptance rates, however, there is an opportunity for more analysis.

The Committee Vice Chair commented that offer filters are a tool to improve efficiency but ultimately, the goal is to decrease non-use of organs and increase organ transplantation. The Committee Vice Chair continued by noting that 100% adoption is not necessarily the goal and there should be consideration for the types of organs that transplant programs accept. For those programs that do not adopt filters, they will be disadvantaged in terms of their metrics. The Committee Vice Chair suggested that for programs that are contacted by MPSC, for example, could provide an opportunity in encouraging those programs to adopt filters. Staff agreed with this and added that these comments will be important to consider as default filters are implemented.

A member asked when normothermic regional perfusion (NRP) information would be implemented in the OPTN Donor Data and Matching System. The member added that this should be incorporated into filters. Staff clarified the release of the data fields is awaiting OMB approval before implementation. The member emphasized the importance of having this incorporated in offer filters because programs are going to treat a regular DCD offer differently from an NRP DCD offer.

Another member asked how acceptance rates used at programs. The Committee Vice Chair explained that the goal is to identify programs that are underperforming and reluctant to accept organs that they should be transplanting. Additionally, as it pertains to efficiency, allocation is delayed if these offers are going to programs that won't accept them since it leads to more cold time and potential non-use of the organ. Programs don't operate based on the offer acceptance rate ratios, it is more a result of a program's performance. The member continued by asking why one program would accept a kidney that another would not. The Committee Vice Chair explained that the variation in offer acceptance is unacceptably high, but it should never be identical. Programs have different resources, different types of patients on their lists, different immunosuppression protocols, etc. Therefore, each physician has to make their own decision about suitability of an organ for their candidate. There are some programs, however, that could improve their transplant volume.

Staff commented that there would be a special public comment period from September 17th – October 16th, 2024 that will include an MPSC sponsored update on post-transplant graft survival metric. There will be a public comment webinar held on September 27th and a goal of bringing the proposal to the Board of Directors in November/December for January implementation.

The Committee Chair asked for more information about how the filters were rolled out, for example, what lung received vs. other organs? Staff replied that filters launched for kidney January 2022. The Committee was involved in terms of monitoring and evaluating the utilization of the tool, and subsequently developed a proposal to turn the filters on by default. The default model was expected to

be implemented this summer originally but other organ groups were requesting filters, particularly for lung following implementation of continuous distribution (CD). The OPTN Executive Committee voted to modify the timeline to delay default kidney filters to roll out basic filters for other organs. The intent is for each organ to continue to consider opportunities to refine and update their filters. There will be new filters coming for kidney with default filters as well as new exclusion criteria. There will be enhanced monitoring reports which will be presented to the Committee. Model-identified filters will be implemented by default but will not be turned on for pediatric-only kidney programs. Candidate exclusions will also be included by default (O-ABDR mismatch, CPRA > 90%, candidate age <18 years, medically urgent status).

A member asked if programs would be notified every six months when the default filters are reset. Staff replied that there would not be direct notifications to programs, but default filters will be loaded into Offer Filters Explorer in advance so users can see what will be turned on and be able to see when default filters are being turned on and off. Staff added that a system notice will be going out in October to prepare programs, and another system notice will be going out in November once the default filters are turned on. Similar system notices would go out in April ahead of the 6-month update.

Another member asked if programs have to make modifications to their offers every six months. Staff replied that if program has modified candidate exclusions, those will be carried over. Programs will not be able to directly modify the default filters; data will be collected to track the change between filter generation periods to evaluate if programs are being recommended the same filters. If a program does not want to use these filters, that respective program will need to take steps to turn them off at the refresh date.

A member asked if the default filters apply to all programs or only those with filters enabled. Staff confirmed that the default filters will apply to all programs except pediatric-only programs. Filters will be turned on for everyone every 6 months but the programs could turn them off. Staff added that HIV+ donor match runs will not have filters applied.

A member asked if this was a bypass vs a decline that influences why a program wouldn't use filters. Staff explained that the offer acceptance rate metric is intended to capture performance for accepting all offers received. Bypasses are used for other reasons as well which is partly why offer filters were designed in that way. The member continued by asking for those programs not using filters, would they have to review all these data themselves? Staff confirmed that this was true and added that some programs also contract with screening services to review their offers, but members have shared they've also heard that transplant programs can offload some of the work for their screening services by using filters. The member continued by stating that there were lots of varying reasons why someone would use a filter or not. Work volume can influence it. To prevent staff burnout, programs can use filters or contract out.

There were no additional comments or questions.

Next Steps:

The Committee will continue to be updated on the progress of the offer filters project.

3. Review and Discussion: Kidney Minimum Acceptance Criteria (KiMAC)

The Committee received an overview of a new project idea centered on incorporating the KiMAC into kidney offer filters.

Summary of discussion:

A member asked how many programs use KiMAC. Staff replied by stating that all programs use KiMAC and must complete the questionnaire. However, programs can provide inputs to the KiMAC that do not actually screen anything further.

Another member asked that if KiMAC were moved into offer filters, would this be forcing programs to use filters? Staff stated that this would be a good question for the Committee to consider. It may be easier for programs to manage if they are working through one tool instead of different tools.

The Committee Chair asked if there was data that compares how much screening is happening with offer filters vs KiMAC. Staff stated that the two tools are challenging to compare. The Organ Center (OC) applies the KiMAC from a certain sequence number on; offer filters could still be applied once OC takes over and is using KIMAC. Staff added that offer filters are being applied as soon as organ procurement organizations (OPO) run the match, including matches that never get to 250 nautical miles (NM), so this would need to be considered with any analysis. In looking at the numbers, offer filters are probably doing more screening because it is being applied first, but some more analysis could probably be done.

Staff stated that the OPTN Kidney Transplantation Committee's Workgroup already did a lot of analysis on this to see which KiMAC criteria are effective screeners, which the Committee would be given the opportunity to review and provide feedback.

A member stated that kidney transplantation is experiencing a lot of changes currently; not just with offer filters, but potentially the IOTA model, and expedited placement discussion. The member emphasized that less tools are better.

The Committee voiced unanimous support in proceeding with this project.

4. Update: OPTN Expeditious Task Force

The Committee was provided an update on the OPTN Expeditious Task Force (Task Force) work.

Summary of discussion:

A member asked if there was any information or impact based on location of the donor. The presenter explained there used to be more time constraints around travel/ischemic time for heart, but with new technologies, that is less than an issue. Kidney candidates are often called into the hospital whereas heart candidates are often already in the hospital. Organs are coming from donor hospitals all across the country.

Another member asked for clarification on whether organs were arriving to the patient and then declined. The presenter replied that this does happen sometimes. For example, an organ may look suitable upon initial evaluation, but once it arrives at the OR, it may no longer seem suitable. The presenter commented that the better we can get at figuring that out early, the more efficiently we can place the organs.

A member shared that at their program, they are re-allocating kidneys 17% of the time because they are declined by the primary program for several reasons. That does not always lead to non-use but may lead to expedited offers. The member asked whether there was going to be a similar study in terms of late declines leading to expedited offers? The presenter confirmed this was the case and reiterated that the Task Force is making efforts to minimize non-use.

The Committee Vice Chair stated that on the transplant program side, the increasing issue are candidates turning down offers that transplant surgeons think are suitable. Burden is on the transplant program to educate patients but challenging when making those calls at 2 am. When that happens 2-3

times in a row when working down your own match run, cold ischemic time builds up. The presenter agreed with this and shared that at their program they are reaching out and holding one on one discussions with patients who are potentially going to receive an organ to talk through those considerations in advance. There is an opportunity to increase shared decision making.

The Committee Vice Chair continued by stating that the discard rate will never be 0% and should not be. A discard rate of 0% would mean we are not doing a good job of procuring organs. A patient does not want to get an organ that is not going to work. The Committee Vice Chair continued by stating uncertainty of what the ideal discard rate should be. The presenter agreed with this and stated that the ideal number may shift as new technologies develop.

The Committee Vice Chair added that kidney donor profile index (KDPI) is a moving target too. 90% KDPI kidneys today are different than those 10 years ago. The presenter agreed with this and added that non-use rate goes up sharply at KDPI of 70% but is not clinically different than KDPI of 65%, so there is an opportunity to improve that measure as well. The presenter added that Hepatitis C Virus (HCV), for example, used to have a big impact on KDPI, but is now treatable and has negligible impact.

A member asked how patients can help and what kind of education could be shared? Another member stated that some patients don't want high KDPI organs. It is uncertain if patients don't understand or if it is the stigma that those organs won't provide 15-20 years. The member suggested that it may be helpful to share that patients are signing up for those organs and having good outcomes. The member continued by adding that it would be helpful to have conversations about those things that have stigma associated (e.g. HCV positive (+) organs). The presenter agreed that patients are often the most important voice for other patients. The Task Force has patients and donor family representatives to help provide perspective, but the member was encouraged to share the messages learned in the meeting to their colleagues/fellow patients.

The Committee Vice Chair stated that a lot can be done just by speaking to other patients. This work can also be magnified at the system level, such as at the OPTN Committee level. Additionally, the member was encouraged in playing a role in advocacy with the various stakeholder organizations. It was emphasized that legislatures need to hear the patient stories to understand the transformative power of transplant.

The presenter stated that the Task Force is not a Committee and does not do policy, therefore the Committee has an important role here to do further work with some of these projects. The presenter mentioned a potential new project idea about data on DCDs that would allow the ability to get the right information in the right place at the right time. The Committee will discuss this project in further detail during an upcoming meeting.

There were no additional comments or questions.

Next Steps:

The Committee will continue to be updated on the progress of the Task Force.

5. Public Comment Presentation: Continuous Distribution (CD) of Kidneys Update

A representative of the OPTN Kidney Transplantation Committee (the Kidney Committee) presented the CD of Kidneys Update; the Committee provided feedback.

Summary of discussion:

The thanks the OPTN Kidney Transplantation Committee for their efforts and update on the Continuous Distribution of Kidney project and the opportunity to comment. The Committee provided the following feedback for consideration:

- "Hard-to place" Kidneys
    - The Committee suggested collecting information to evaluate surgical damage. There are programs willing to accept these kidneys and this information would be useful. Additionally, the Committee discussed anatomical characteristics that should be considered in defining "hard to place" kidneys that include kidneys with three or more arteries, and kidneys with large hematomas or perinephric hematomas.
    - The Committee also suggested consideration of donor characteristics such as diabetes, hypertension, age, and creatinine, which can also result in kidneys being hard to place. All of this information is readily available at the beginning of the offer being sent out; it was suggested the Kidney Transplantation Committee consider developing a pathway that incorporates this information at the start of the organ offer process in an efficient and fair manner.
    - There was a suggestion to incorporate pump numbers (specifically the initial set of pump numbers); a member stated that there are times when a program is waiting for pump numbers and then later decline the offer due to this.
    - The Committee also discussed and voiced concern that the root cause is not clearly identified. It is being observed that programs are putting in provisional yeses in and then declining post-recovery due to information that is already known (creatinine, medical history, etc.). These processes can be done but OPOs will still be under scrutiny. There needs to be a solution in how to have programs truly review the offers if they are primary.

- Expedited Placement:
    - The Committee suggested that expedited placement not start at 5 hours cross clamp due to lack of information available during that time. It was recommended that expedited placement not exceed 9 hours due to there being observance of the increased risk for non-use of that kidney; additionally, this provides a buffer when considering logistics such as transportation to get the kidney to the accepting hospital within 12 hours. The Committee added that there is a need to clearly define expedited placement before determining how this process would be operationalized.

Next Steps:

The Committee's feedback will be submitted for public comment for the Kidney Committee's consideration.

6. Wrap Up/Continued Discussion: KiMAC

The Committee continued their discussion on the KiMAC project idea by reviewing previous decision points and providing additional feedback/recommendations.

Summary of discussion:

Staff reviewed the previous work and recommendations made by the OPTN Kidney Transplantation Committee's Workgroup in refining the KiMAC criteria to carry forward into CD. In review of the PHS risk criteria, the Committee was asked if the criteria was too granular to be used for screening. The Committee Chair stated that this information was not relevant. A member stated that the individual reasons do not matter because from experience, there are surgeons who look at the granular information and will not accept organs based on various testing window. Another member stated that there is a pandemic of drug overdose deaths and added that these details are largely not a defining component in making a decision on an offer. The risk of transmitting human immunodeficiency virus (HIV) is low and these risk factors would not be a reason to decline a kidney.

Staff asked if these criteria should be available as potential filters. A member stated that it is challenging to get people to agree at the program level. Surgeons would have different opinions on this. Additionally, there would need to be consideration on complexity; there are too many questions. It was suggested that "PHS high risk or now" would be easier to manage. The member continued by stating that there is a movement to get away from this construct of high risk consent because patients absorb "high risk" and are not receptive to further education/information.

Another member inquired about how much of this information that patients know. The Committee Vice Chair stated that patients have to know this information in order to give consent.

In review of the infectious disease test results, the Committee recommended excluding syphilis. A member asked if the KiMAC automatically applies to everyone. Staff replied that KiMAC applies to everyone over 250NM away except for those who are high panel reactive antibody (PRA) or 0-ABDR mismatch.

The Committee Chair asked if KiMAC applies to pediatric offers. Staff stated that it would apply to pediatric candidates. It is rare that KiMAC is being applied to Sequence A or B kidneys (those sequences which pediatrics are prioritized for). The Committee Chair continued by asking for clarification on whether or not pediatric programs could choose to use offer filters. Staff confirmed this.

In review of the minimum donor creatinine clearance level upon donor's admission, a member stated that this information did not seem helpful if there would be more accurate data available with the other filters like terminal creatinine. The member continued by stating that glomerular filtration rate (GFR) cannot be estimated accurately without stable creatinine.

The Committee was asked if they would consider an adult kidney donor with known history of polycystic kidney disease. A member replied that this seemed to be out of scope of practice and added that there would be the ability to determine relevant information from other data points.

The Committee reviewed the next section (anatomy). The Committee recommended excluding these criteria and explained that this goes into center-level decision-making. The information is subjective to the person reviewing the case and would not be appropriate for filtering.

A member stated that if information isn't posted until 6 hours post-cross clamp, it is uncertain that it will actually make a difference in terms of reducing non-use. The Committee Chair agreed with this and stated understanding as to why it is used when moving beyond 250 NM but not sure it is going to filter off anything in offer filters because that info won't be available until later.

Staff asked that in thinking about transitioning KiMAC, if a program has a filter in place that says they do not want to receive a donor from over 250 NM with severe hard plaque, that would essentially be screening in the same way that KiMAC screens it now but would be more automated. A member asked

how effective this screening was currently. Staff stated that they could pull the data for the Committee to review. The Committee agreed in not wanting to make things worse and that if the data shows that this is currently helpful, they recommend keeping this information.

The Committee then reviewed the next section (Uncontrolled DCD donor). The Committee Vice Chair commented that this must involve small number and recommended not imposing data burden for small gain. A member asked about whether this information was currently collected in the OPTN Donor Data and Matching System. Staff clarified that these data fields are currently pending implementation for OMB. Another member stated that there is variability in how OPOs define uncontrolled donors; the Committee recommended excluding.

The Committee recommended to keep the history of hypertension and compliance with medication. A member asked if there was an option for unknown history. Staff will add this comment as a consideration.

For diabetes duration and management, a member stated that they look at A1C to understand if diabetes was controlled or not without the OPO having to figure this information out. The member continued that this could also be done based on Hemoglobin A1C instead of managed with insulin or oral medication. The Committee recommended excluding this but incorporating Hemoglobin A1C.

There were no additional comments or questions. The meeting was adjourned.

Upcoming Meetings

- October 24, 2024 (Teleconference)

Attendance

- **Committee Members**
  - Kim Koontz
  - Steven Potter
  - Annemarie Lucas
  - Amanda Bailey
  - Bridget Dewees
  - Anja DiCesaro
  - Sarah Koohmaraie
  - Alden Doyle
  - Elizabeth Shipman
  - Jillian Wojtowicz
  - Anne Krueger
  - Kaitlyn Fitzgerald
  - Norihisa Shigemura
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Kaitlin Swanner
  - Susan Tlutsy
  - Kayla Temple
  - Laura Schmitt
  - Rob McTier
  - Carlos Martinez
  - Betsy Gans
  - Kerrie Masten
- **Other Attendees**
  - Arpita Basu
  - James Dewees