OPTN Operations & Safety Committee
Meeting Summary
September, 28 2023
Detroit, MI

Alden Doyle, MD, MPH, Chair
Kim Koontz, MPH, CTBS, Vice-Chair

Introduction

The Operations and Safety Committee ("Committee") met in Detroit, MI on 09/28/2023 to discuss the following agenda items:

1. Post Public Comment Review: Deceased Donor Support Therapy Data Collection
2. Review and Discussion: Reporting Device Failures
3. Update: Efficiency Project Efforts
4. Discussion: Redefine Provisional Yes
5. Discussion: Project Idea Referral
6. Update: Post Cross-Clamp Test Reporting

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

1. Post Public Comment Review: Deceased Donor Support Therapy Data Collection

The Committee reviewed their public comment proposal, "Deceased Donor Support Therapy Data Collection".

Presentation Summary:

The proposal aimed at enhancing data collection by adding seven new data fields within the Donor Data Matching System. The objective was to streamline the integration of this data into the OPTN's data system. It was also proposed to replace the existing extracorporeal membrane oxygen (ECMO) data collection field with a group of data flows to centralize data collection. This centralized approach was designed to simplify data collection and organ offer review.

Summary of discussion:

The Chair noted their appreciation for the substantial amount of feedback received during the public comment period. The Committee engaged in extensive discussions based on the received feedback. The proposal was presented and discussed in all 11 regional meetings, and feedback was gathered through virtual exchanges. Various stakeholders, including transplant administrators, transplant coordinators, and blood transplantation representatives, provided valuable insights. Additionally, feedback from five organizations added depth to the discussion. Overall, the sentiment regarding the proposal was positive. The majority of comments expressed strong support for the proposal's objectives. Feedback highlighted the potential benefits, including improving organ allocation, enhancing the evaluation of organ offers, and supporting transplant research and innovation. Stakeholders recognized the need for this data collection, particularly due to the lack of a centralized platform for reporting it. The comments echoed a desire from the Committee to streamline and optimize data collection practices.

While feedback on the placement of data fields was limited, the proposal suggested positioning the fields on the "Meds and Fluid" page. A member proposed the tab be renamed, "Baseline Donor

Management," noting that the data captured were not medications or fluids. The Committee acknowledged that the majority of responses indicated satisfaction with the proposed placement, especially on the "Meds and Fluid" page.

A noteworthy aspect of the feedback was the trend towards adding granularity to the data fields. Suggestions included specifying various types of dialysis and providing additional details about dialysis modality. The Committee faced a balancing act, considering whether to maintain simplicity or incorporate a level of granularity that would be both useful and user-friendly. Some members proposed the idea of incorporating a drop-down menu for specific data, which could strike a balance between simplicity and detail. Concerns were raised about providing sufficient information without overwhelming the users with too many data fields. The Chair recognized the challenge of achieving a balance between being too high-level and rendering the fields less usable due to specificity. However, he emphasized the importance of accommodating public comment requests for more granular data while keeping the data collection process user-friendly; In particular, the level of granularity required for categories such as continuous dialysis, acute versus chronic status, and the types of therapy administered was highlighted.

One member suggested a potential solution of introducing a "yes or no" option in the data fields, followed by a drop-down menu with more granular options if available. This approach would allow users to access more specific data when required, but not overwhelm them with excessive choices. Suggestions were made to introduce drop-down menus to provide more specific options, particularly in data fields like "Inhaled Therapies." The consensus was to make it more granular to capture a variety of therapies effectively.

The Committee recognized that certain detailed clinical information might necessitate referring to the clinical chart for full context. Dialysis details, including the modality, frequency, and duration, were noted as important factors in evaluating an organ offer, especially considering whether the patient required ongoing renal replacement therapy, and would be present for programs to review in detail in the chart.

Members considered the elements that are most critical for determining the next steps regarding organ acceptance or decline. It was noted that certain categories like continuous dialysis, acute or chronic status, and certain therapy types were highly significant in this context.

The Chair introduced the topic of anti-coagulation therapy and explored the implications of capturing related data. The discussion considered whether specifying the type and administration of anti-coagulation therapy was necessary for decision-making or if a broader categorization would suffice. The complexity of drip therapy and the potential need for checking clinical charts would make summarizing the information in a usable way when evaluating offers difficult.

A key aspect of the discussion revolved around patients who are transferred between different healthcare facilities during their care. The importance of distinguishing between terminal events and previous admissions was highlighted, as well as the need to ensure that support information was captured throughout the entire event, not just the final hospitalization. A member emphasized the need to maintain an inclusive approach in data collection, covering various support devices and allowing for the incorporation of new types of support devices as the field evolves. The proposal aimed to categorize support devices and provide drop-down menus for different types to ensure comprehensive data collection. To do so, they felt the Committee should pursue clear data definitions and distinctions. The proposal will not overlap with the current data collection asking about the use of ECMO.

It was suggested that the OPTN should collaborate with vendors to ensure an efficient transition of medical records data into the system. This collaboration would help streamline data entry and extraction.

Transplant center comments raised concerns about potential changes impacting the assessments of composite allocation scores. Staff addressed these concerns, clarifying that the proposed modifications wouldn't affect these scores.

There was a consensus that "Terminal Event" should be used to specify all stages of data collection rather than just focusing on admissions. This would accommodate cases where a patient is transferred multiple times, providing a comprehensive view.

The Committee reviewed data definitions. A member suggested clarifying "Ongoing Until Cross-Clamp" since a distinction between the date and time was raised. The proposal will be clarified, ensuring a clear understanding of the data entry for ongoing therapy. The definition of "Inhaled Therapies" was discussed. The consensus was to make it more generic to capture other potential therapies beyond nitric oxide. It was suggested to define it as "Any inhaled therapy for active support."

With no further discussion, the Committee voted to submit their proposal to the Board of Directors (13 yes, 0 no, 0 abstain)

Next steps:

The Committee will present their proposal to the Board of Directors at their winter 2023 meeting.

2. Review and Discussion: Reporting Device Failures

The Vice-Chair introduced the next topic, an overview of the discussions surrounding device failure issues that had been brought to the attention of Committee leadership.

Presentation Summary:

As of the meeting, five perfusion device-related cases had been recorded. Their details were provided to the Committee for review.

Summary of discussion:

Members noted the need for clarifying the reporting responsibility between the organization and the Food and Drug Administration (FDA). It was noted that it's essential to report device failures, but the role in policing device manufacturers isn't within OPTN purview. The lack of comprehensive data was emphasized. Currently, reporting is voluntary, and there is a need for efficient data collection to evaluate device failure issues. Potential considerations were discussed to make reporting of device failures mandatory. Collecting this data could help inform guidance, education, or recommendations.

A member highlighted the importance of notifying the FDA about device failures. The Committee noted that, in addition to reporting to the OPTN, this information should reach the FDA for proper tracking and analysis. A suggestion was made to make it easier for members to report device failures to the FDA. Adding a link or instructions within the OPTN patient safety portal was discussed to facilitate reporting to the FDA. This will aid the OPTN in gathering comprehensive data on device failures to address these issues proactively.

During the discussion, the importance of reporting surgical damage, not just when organs are lost, was highlighted. The Vice-Chair supported capturing near misses or errors that lead to organ damage, as these are considered valuable for improving practices and reducing risks.

A member also highlighted the complexity of communication challenges in the transplant field. It can be challenging to determine where improvement is needed, dissect what went wrong, and address miscommunication effectively. The Committee recognized that, during reviews, there are often very different perspectives on what occurred, leading to vague recommendations like "better communication."

Issues were raised concerning organs that are allocated but subsequently turned down, which may result from expected damage or miscommunication. Members stressed the importance of capturing and defining late declines, such as organs that were accepted but declined later, which currently might not be captured effectively. There was a suggestion to encourage both recovery and transplant programs to use visual documentation, such as photographs or videos, to verify issues during the process. Visual documentation, it was noted, could resolve disputes and aid in understanding what transpired during an event. The need for standardization in practices, like the timing of decision-making and the information required to make decisions, was also recognized. Streamlining decision processes could lead to better efficiency and patient safety.

Next steps:

Staff will return the feedback and recommendations to the cross-committee leadership team to determine the next steps.

3. Update: Efficiency Project Efforts

Staff provided an update on the task force to address efficiency.

Presentation Summary:

The task force's goal is to enhance organ utilization and reduce discard rates. The task force, co-chaired by the Committee's chair, is responsible for providing updates, fostering discussion, and generating recommendations for the transplant community. Efficiency is a multifaceted goal, encompassing various aspects of the organ transplantation process. The discussion acknowledged that recent developments, such as the shift from direct service area (DSA) to continuous distribution, organ-specific committees, and the need for efficient organ allocation, have highlighted the urgency of addressing these issues.

Summary of discussion:

Concerns were raised about the high non-use rates, particularly for kidney transplants. Non-use rates remain unacceptably high, impacting organ donors and their families. The meeting noted the need to address these issues and the inefficiencies associated with organ allocation. Variability in the behavior of different transplant centers was recognized. The discussion emphasized that some transplant centers often accept organs out of sequence, leading to inefficiencies. It was acknowledged that more systematic approaches were needed to address the hard-to-place organs. The task force aims to work alongside existing committees and provide insights and ideas to improve the efficiency of organ transplantation. The group will work with a larger team of experts, including individuals from various industries, to address efficiency challenges. The focus will be on continuous improvement and pilot projects.

The task force will report directly to the OPTN Executive Committee, the OPTN President, and OPTN Vice President. The task force structure will work closely with existing committees but focus on providing recommendations for efficient practices, pilot projects, and industry expertise. The goal is to provide ideas and solutions quickly. Committees will continue to focus on their policy work and operational tasks. The task force and committees will collaborate as needed to address efficiency-related issues.

The task force seeks to have broad representation from various stakeholders, including patients, donor families, the transplant community, and regional representation. To ensure diversity and a balanced perspective, the task force is working on appointing members from all regions in the United States.

The task force is committed to transparency and community engagement. They are setting up a web page for updates, creating a portal for idea submissions, and seeking input from various stakeholders.

Members discussed how they could effectively interface with the newly formed task force focused on efficiency. They acknowledged that the Committee has extensive experience and institutional memory concerning the issues that the task force aims to address. They emphasized the need for the Committee to contribute ideas and insights to inform the task force's work.

A member also noted the importance of reviewing their existing projects and how they can align their work with the goals of the task force. They mentioned ongoing work related to the redefinition of the provisional "Yes" project.

Members expressed their interest in brainstorming ideas and projects related to efficiency that they believe the task force should consider. They highlighted the need for a more comprehensive approach to address efficiency issues, such as data collection, pilot projects, and collaboration with transplant centers. One key focus area discussed was the importance of data analysis and reporting. Members emphasized the need to gather and analyze data on at-risk organs and non-utilized kidneys. This data could provide insights into why some kidneys are discarded while others are successfully transplanted. The committee highlighted the need for greater transparency and data-driven improvements in organ allocation.

It was also proposed to examine the machine perfusion of organs, focusing on documentation, communication, packaging, and labeling. Members recognized that this is a critical aspect that requires well-defined guidelines to enhance efficiency in the transplantation process.

A member suggested the need for a specialized allocation system to prioritize at-risk or complex donor organs. They recognized that such organs require a different approach for placement and allocation to ensure they are used effectively. This approach may involve separate allocation pathways and guidelines for these organs. Two members emphasized the importance of treating organ non-use as sentinels and collecting data from these cases to identify areas for improvement. They suggested that every case of non-use should be considered a learning opportunity, and the data could provide valuable insights to enhance efficiency in organ transplantation. They added that having clear, shared criteria for organ non-use could help transplant programs make decisions that are consistent and beneficial.

The Chair emphasized the value of learning from other systems, both within and outside the United States. They noted that sharing best practices and data collection approaches could improve the organ allocation process.

Next steps:

The Committee will submit project recommendations to the task force for review and dissemination to the appropriate OPTN committee.

4. Discussion: Redefine Provisional Yes

The Committee broke into small groups to discuss approaches to addressing Provisional Yes. They then reported back out a summary of their discussions.

Presentation Summary:

The project aims to redefine and improve the efficiency of organ offer and acceptance practices, with a focus on the provisional "yes" response. The project addresses the issue of transplant programs sending a high number of offers to transplant centers, leading to overwhelming provisional "yes" responses, which may not necessarily lead to the acceptance of offers.

To address this issue, the project initially developed a tiered framework to clarify the responsibilities and requirements associated with a provisional "yes." The framework outlines different tiers of provisional

responses, each with its own set of requirements and responsibilities. As transplant centers progress through the tiers, the requirements become more rigorous. The goal is to reduce provisional "yes" responses that don't lead to actual organ acceptance. Feedback received from the community during public comment suggested that the tiered system, while conceptually valid, was perceived as complicated and potentially overwhelming.

Highlighted areas from public comment were:

- The need to prioritize and simplify the implementation of offer filters to improve offer and acceptance practices.
- Offer filters are tools that transplant programs can use to screen out offers that don't meet their criteria and may take some of the burden off the tiered system. OPTN members supported enhancing education and awareness about offer filters to help transplant centers use them more effectively.

The Committee is exploring whether the project should be broken down into smaller, more manageable pieces rather than one complex initiative. Sequencing and simplifying the project to make it more digestible for the community are under consideration.

Summary of discussion:

The focus of the first working group was on defining the responsibilities of transplant programs. They discussed the need to have various levels of responsibility for transplant centers when accepting an offer, whether it's an original "yes," being on deck, or other defined stages. The aim was to make these responsibilities more efficient and understandable. They also suggested the idea of having alternative organ placement strategies when the traditional system may not be working optimally. They proposed the need for guidelines or frameworks to implement these strategies when required, considering specific criteria. There was a general agreement on the need for more automated systems in the organ placement process. Members also touched on the use of hypothermic profusion technology and the importance of defining time parameters for various stages in the process.

The second working group addressed the responsibilities of the Organ Procurement Organization (OPO). They noted the importance of understanding why transplant centers send a specific number of offers and considered predictive analytics as a tool to optimize offer numbers sent by the OPO. The discussion highlighted the need for standardizing definitions, particularly around "late decline." This would help establish criteria for what constitutes a late decline and encourage the consistent entry of relevant data.

The group also recognized the need to review and update the information required to make an offer. The goal was to establish consistency in the amount of information provided to transplant centers during the offer process.

Members highlighted the importance of tracking information when transplant programs initially respond with a provisional "yes." They further emphasized the significance of avoiding later changes in response to readily available information. Considerations included defining the parameters for when an offer should be considered expedited and establishing expectations for different timing scenarios. The group also explored the idea of incorporating offer comments, allowing transplant centers to communicate specific needs or requirements related to the offer. This could enhance the efficiency of the process and reduce the need for back-and-forth communication.

A member considered that predictive analytics could alleviate center-level variance in practice, particularly in the context of transplant center behavior across different regions. Predictive analytics

could provide insights into the likelihood of an organ being placed based on the region and help inform transplant center decisions.

The third working group aimed to clarify the definitions of primary, secondary, and third backup offers, making distinctions based on the match run. The group prioritized the need to find a solution for making transplant centers aware of where they stand in the process. Since the status can change quickly, it was suggested to clarify the responsibilities for primary, secondary, and tertiary backups. Furthermore, they noted a need to communicate that offers and responsibilities are dynamic and can change throughout the allocation process.

The group discussed the potential stigma associated with new Organ Procurement Organization (OPO) performance metrics tied to the term "tiers." To address this, they proposed using the terminology of primary backup, secondary backup, and tertiary backup instead of tiers.

While the term "multi-organ" was considered self-explanatory to clinicians, the group acknowledged the need to incorporate plain language into definitions to ensure clarity, particularly for patients who may not readily understand the term. It was suggested that multi-organ should have a clear pathway for both backup and post-facto review when a multi-organ transplant is refused.

The group also recognized the importance of selecting either "decline" or "refuse" consistently and sticking to one term throughout. They also discussed categorizing refusal codes into three broad buckets: donor-related, recipient-related, and program-related reasons. The focus was on avoiding overly detailed codes for the sake of simplicity. A member noted that the Committee should carefully consider endorsing losing granularity through refusal code options.

For primary backup situations, it was suggested that centers should assess all available donor information at the time of a provisional "yes" and that any information known at that point should not become a reason for later declines. This approach could help monitor and prevent center behavior involving frequent provisional "yes" followed by later declines. For final acceptance, candidate availability and contact should be ensured.

The fourth group examined the time limit required for organ offers. Members raised differing opinions about the number of offers and the need for a policy solution to define optimal numbers. Some members felt that it would be impossible to define a static number of offers allowable, while others noted that there can be a dynamic amount allowed at different stages of the allocation process. There was overall agreement on applying offer filters to all organ types. The importance of text message notifications for coordinators, particularly when provisional "yes" changes to a "no," was highlighted, noting the speed difference between a text message and a phone call. Members also touched on standardizing the “notify primary” button usage to create consistency among transplant centers. A member also suggested automating the offer notification process.

5. Discussion: Project Idea Referral

The Committee reviewed potential project ideas.

Summary of discussion:

The Chair introduced the potential project idea to revise OPTN Policy 16.6: *Extra Vessels Transplant and Storage.* It is proposed to centralize the tracking of extra vessels and clarify the storage requirements. Members agreed that extra vessels are essential and should be managed by the OPTN; they also endorsed the idea of using technology to track vessels, including labeling, ensuring traceability and safety like how organs are tracked. A member suggested running a “mini-match run” to accommodate

blood type compatibility. The Chair added that addressing the use of Hepatitis C and Hepatitis B positive extra vessels may make this process easier.

The Committee considered a referred project on organ labelling. Members noted that information contained on organ labels are inconsistent with the information required by the OPTN Donor Data and Matching System. The Vice-Chair felt that this was a straightforward issue and discussed the possibility of directly fixing it without a policy proposal by aligning the information required on the label and the information required by policy. Staff will return to the Committee as to whether this requires a policy proposal.

A member introduced the project on blood type timing determination. The project centers on the need for clarity regarding blood typing determination Pre- or Post- transfusion. The current policy, while outlining blood typing requirements, does not specify the timing of the blood draw, leading to potential patient safety risks. The proposed solution is to add a checkbox in the system indicating whether the blood draw was done Pre- or Post- transfusion, thus standardizing communication and reducing the risk of patient safety concerns. Standardizing the process is essential for efficiency, ensuring that information regarding transfusions is consistently documented, reducing the chance of oversight.

A member noted an instance reported where incorrect information about blood typing, Pre- or Post-transfusion, led to concerns about compatibility with the recipient. They felt this incident highlights the potential patient safety risks associated with the lack of standardized communication.

While the urgency of this project was discussed, members were split on how to prioritize it alongside the Committee's other projects. However, it was recognized that clarity on this issue is essential for patient safety.

Members extrapolated the project's core idea into considering options for standardizations or improvements in the data fields and user interface. This could involve looking at additional details such as the type of blood transfused to further enhance the efficiency and safety of organ offers. This would also align with the Committee's existing efforts to improve the data availability for reviewing organ offers. The Vice-Chair also suggested providing it as a recommendation to another committee investigating patient safety data standardization.

Next steps:

Staff will aggregate the Committee's recommendations into project forms and provide replies on referred projects.

6. Update: Post Cross-Clamp Test Reporting

Staff presented an update to the Post Cross-Clamp Test Reporting project.

Presentation Summary:

The Post-Cross Clamp Test Reporting project started its development as of July 31st. The development will include implementing all the functions tested during the pilot project. The team is working to enhance the system by creating new permissions and a mobile-friendly feature to acknowledge test results. Additionally, the project aims to provide a report on acknowledged tests, which transplant centers can access for historical data. Educational courses related to the project will be made available in the UNet Courses. These courses will help transplant centers learn how to use the system effectively. Using the project will be voluntary initially, but it may become mandatory in the future depending on the community's response. The national rollout of the project is planned for the first quarter of 2024.

Summary of discussion:

A member noted the need to consider different user groups who may be involved in reporting and post-crossmatch testing. Permissions will be designed to accommodate various roles within transplant centers.

Next steps:

Staff will apprise the Committee of any updates to the timeline.

Upcoming Meeting

- October 26, 2023 (Teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Andy Bonham
  - Jill Campbell
  - Kaitlyn Fitzgerald
  - Julie Bergin
  - Anja DiCesaro
  - Anne Krueger
  - Mony Fraer
  - Stephanie Little
  - Annemarie Lucas
  - Snehal Patel
  - Norihisa Shigemura
  - Jillian Wojtowicz
- **HRSA Representatives**
  - Jim Bowman
- **UNOS Staff**
  - Joann White
  - Robert Hunter
  - Roger Brown
  - Laura Schmitt
  - Betsy Gans
  - Carlos Martinez
  - Kerrie Masten
  - Kevin Daub
  - Amy Putnam
  - Carson Yost
  - James Alcorn