OPTN Data Advisory Committee
Meeting Summary
March 22, 2024
In-Person Meeting Houston, Texas

Sumit Mohan, M.D, M.P.H., Chair
Jesse Schold, PhD., M.Stat., Vice Chair

Introduction

The OPTN Data Advisory Committee met in-person in Houston, Texas on 03/22/2024 to discuss the following agenda items:

1. Update on OPTN Data Quality
2. Deceased Donor Data Collection Work
3. MPSC Referral: Transportation Issues-Discussion and Decision
4. For DAC awareness: Network Operations Oversight Committee – Revise Conditions for Access to the OPTN Computer System
5. OPTN Strategic Plan Proposal Follow-up: Data Collection Objective
6. Accessing Kidney Data and Graft Failure Information
7. Potential project ideas: DAC priorities, review list of projects, and time for members to discuss ideas.
8. HHS Directive update: Next steps
9. Review 24-month Refusal Code Monitoring report (final monitoring report)

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

1. Update on OPTN Data Quality

The OPTN Contractor shared updates on the bolded recommendations below. These short-term recommendations were provided to the OPTN Board of Directors by the DAC Chair on November 29, 2023.

Data summary:

The short-term (1-2 years) recommendations for improving OPTN Data Quality include the following:

- Review transplant programs that are unlocking/editing data at higher rates to determine what action is needed (e.g., education, additional monitoring, enhancements, etc.)
- Perform additional analysis to understand the correlation between member data submission approach (electronic or manual) and unlocking activities
- Monitor and work with programs that have high rates of inconsistencies in dialysis dates to identify ways to reduce error rates

As part of DAC's 2023 Annual Data Report, one of the action items was to follow-up with a sample of OPTN members to discuss the data lock policy and the members' unlocking activities. OPTN Contractor staff contacted OPTN member programs with high unlocking forms and the desire to have a diverse

selection of member sizes based on total transplant number. “Delayed reporting due to staffing resource issue” was the explanation members gave most often for unlocking a form.

Outlier unlocking rate was caused by outlier circumstances. Each OPTN member contacted reported unique situations that helped lead to high unlocking activity. Forms being unlocked multiple times was likely caused by members starting their forms after the 90-day reporting period. When a form is started after the 90-day submission window has closed and changes are required due to validation issues the form will need to be unlocked each time it is changed.

The OPTN members contacted expressed little opposition to the potential of a hard data lock after 6 or 12 months. Members reported rarely or never going back more than a year to change data. Two of the four contacted members were unaware data lock reports are available on the Data Services Portal. After reviewing what was available, members reported that they would likely start using the reports. One member reported desiring a longer reporting period (120 days). The other three members liked the current expanded timeframes implemented in August 2022 and reported the time given being adequate.

As it pertains to the data lock, OPTN Contractor staff plan a second round of member meetings. The goal is to learn more by meeting with subset of high unlocking rate members that regularly utilize the “Internal Auditing Results” unlocking explanation and Members who utilize UNOS API’s and need to correct data. Additional recommendations captured during the first round of review were as follows; promote the use of data lock reports and dashboard available on the Data Services Portal, perform analysis into a potential timeframe for imposing a hard lock, and to consider adding “Validation Issues” to the explanation reason choice list.

In November 2022 CMS (Centers for Medicare & Medicaid Services) changed the way external entities could access their data. This temporarily cut off Organ Procurement and Transplantation Network (OPTN) access to their data which was instrumental to OPTN dialysis reports. The dialysis reports on the Data Service Portal still function but the data has not been updated since November of 2022. Recently access to the CMS datasets has been regranted and updated data will populate the dialysis reports soon. Analysis will be run on the updated CMS dataset and members with high rates of dialysis date and status discrepancies will be identified and some interviewed.

Summary of discussion:

The Chair wanted to have more clarification on the unlock event as it pertains to the entirety of the form. A member of UNOS staff clarified that it is the entire form. When one completes the form, after 90 days (about 3 months) it becomes locked. Another member added that the core issue here is that if a center does not submit a form within the 90-day deadline, the form gets locked automatically. Then if they need to make any changes after that, they must go through the process of unlocking the form, which creates extra work. The unlocking process for completing late entries may result in multiple unlocking events until the entire form is validated. We do not fully understand the unlocking patterns between OPTN members with and without APIs.

A member added to this that there is inconsistency between the data. There is an inconsistency between the data being reported to CMS and the actual source data, specifically around dialysis start dates. The current process of centers having to manually find and reconcile this data which is passive and error prone. CMS may have access to more accurate dialysis data that could potentially be shared back with UNOS to populate this field automatically. Another member advised that tracking post-transplant patients who return to dialysis is also an important data need that CMS historically provided. The Chair advised that the "data lock" process, where data cannot be changed freely, was implemented, in part to ensure modeling viability. However, this has created challenges. There needs to be a balance between hard data locks for completed forms and providing pathways for legitimate data corrections when needed.

The OPTN Contractor discussed encouraging/facilitating API data integration could reduce manual entry errors. For long-term post-transplant follow-up, reducing required data fields in the first 5 years could help ease burden on larger centers.

Next steps:

None were discussed.

2. Deceased Donor Data Collection Work

The OPTN Contractor reviewed and discussed the Deceased Donor Data Collection Work Project.

Data summary:

OPTN Deceased Donor Registration (DDR) Form asks for OPOs to identify cause of death, mechanism of death, and circumstances of death, for all deceased donors. Some of these fields are among the oldest in OPTN data collection. OPTN committees have changed these elements over the years, but OPTN lacks sufficient definitions and documentation. Committee projects currently seek to add/change field options, but the existing state makes this challenging.

There are numerous terminology issues. The first being is that “cause” is a generic term. All causes of death are mechanisms, and all mechanisms are causes. All circumstances listed are also causes. Another issue is that “Circumstances of death” is an undefined term. Some terms can be unclear without further detail for example “Cardiovascular” and “Anoxia”. Some causes/mechanisms/circumstances listed can be secondary to others such as “Cardiovascular”, “Cerebrovascular/stroke”, “Seizure”, and “Anoxia”.

The current state of data definitions are as follows: Cause of Death: “Select the cause of death”, Mechanism of Death: “Select the mechanism of injury” and Called “Mechanism of Injury” in Donor Net, Circumstances of Death: “Description of incidents preceding the death of a deceased donor” and “Select the circumstances of death”.

These fields are then used as follows: Cause of Death: Required to run match (KI) or prior to electronic offer notification (all other organs), Shown on match, Required on DDR, and Indicator of stroke death used to calculate KDRI/KDPI. Mechanism of Death: Not required to run match, shown on match, and required on DDR. Circumstances of Death: Not required to run match, Not shown on match, Required on DDR.

Other Elements in Cause of Death include the following: Major Body Region of Injury: Head Trauma. Mechanism of Death: Anoxia, Cerebrovascular/Stroke, and CNS Tumor. Unclassifiable: Other, specify.

Other Elements in Mechanism of Death include the following: Natural Causes: Cardiovascular, Seizure, Intracranial Hemorrhage/stroke, and Death from natural causes. External Causes/Injuries: Drug intoxication, Asphyxia, Drowning, Blunt injury, Stab, Gunshot, and Electrical. Undetermined/Unknown Manner: SIDS and None of the Above.

Other Elements in Circumstances of Death include the following: Manner of Death, Suicide, Homicide, Child abuse, MV accident, non-MV accident, and Death from natural causes. Mechanism of Death: Motor vehicle accident, non-motor vehicle accident, Unclassifiable and None of the above.

Potential Alternatives:

- Use least number of fields possible; never collect same information twice
- Provide clear definitions for every field and data element
- Use skip logic or validation rules to ensure more accurate data collection
- Make documentation and training available to members to standardize reporting
- Account for sources of data available to OPOs at the time of donor evaluation
- Design for use in OPTN policy evaluation/performance monitoring
- Document fields in a way that acknowledges multiple causes may be at play
- See terms/concepts that are mappable to the existing classification systems.
- Design to facilitate better evaluation of donor potential

Summary of discussion:

The OPTN Contractor discussed that there is a lack of clear definitions and standards for these fields, leading to arbitrary and inconsistent data entry across OPOs and transplant centers. Some of these fields (like circumstances of death) are not readily visible or utilized during the organ match process, raising questions about their utility. There is a need to better align these fields with existing taxonomies and standard processes used by entities like CDC for classifying causes of death. Granular details around mechanisms like drug overdoses, accidents, injuries etc. are important for evaluating donor risk and expected outcomes for different organ types. Different organ types (e.g. kidney vs heart) may prioritize different aspects of this data when evaluating donors.

The OPTN Contractor identified that OPOs currently must make their own interpretations when mapping reported information into the required OPTN fields. Aligning definitions and data fields with other efforts could help standardize approaches. Structuring the data collection flow to follow clinical decision-making processes could facilitate quicker data review by transplant centers. In summary, there was agreement that refining and standardizing these death-related data elements in a clinically meaningful way, aligned across organizations, could improve data quality and utility for donor evaluation and research purposes. However, achieving this will likely require a coordinated effort to develop clear guidelines, taxonomies, and data models.

Next steps:

Develop draft data collection proposals. Solicit Organ Procurement Organization Committee feedback. Prepare for potential public comment in winter 2025and submitting a proposal to the OPTN Board in June 2025.

3. MPSC Referral: Transportation Issues-Discussion and Decision

The Chair and Vice Chair presented on the MPSC Referral: Transportation Issues.

Data summary:

The Membership and Professional Standards Committee's (MPSC) Required Reporting in Patient Safety Events (August 2023) project proposed requiring submission of various transportation events to Patient Safety Portal. MPSC concluded transportation events could not be adequately collected/evaluated through the Patient Safety Portal and referred matters to the Data Advisory Committee and the Operations and Safety Committee for consideration of a data collection project associated with transportation events.

As part of the current process, transportation events are submitted to the Patient Safety Portal and investigated by OPTN Contractor staff for policy violations and patient safety concerns. Cases where a policy violation or patient safety concern is identified are submitted to the MPSC for review. Information about the event is collected on the Patient Safety Portal form, which is OMB approved.

Summary of discussion:

The OPTN Contractor recognizes this is an important issue that needs to be examined, especially with the move to continuous distribution models creating more logistical challenges. However, the Committee agrees that the operational details and project management should be led by the Operations and Safety Committee, with the Data Advisory Committee providing support and recommendations. For data collection it's important to include broad representation from different regions, OPOs, transplant centers, and transportation vendors to get a comprehensive perspective. Potentially starting with a pilot project in a specific region to scope out data needs. Leveraging any existing data from transportation vendors, though it may not capture all near-miss details. Focusing on what data is actionable and can drive process improvements.

Members advised that there is a need to determine intended aims - is the data for oversight/accountability of vendors, improving logistics pathways, public reporting, or allowing market forces? Real-time organ tracking capabilities should be examined and potentially mandated. Late turndowns and their impact on allocation should also be an area of analysis. A member advised that other groups like OPOs and MPSC may need to be involved given the cross-cutting nature. Policy and funding considerations around mandating tracking or holding vendors accountable need scrutiny. A member suggested extending the scope of an existing OPTN late turndown analysis project to also look at transportation near-miss data. In essence, while the Data Advisory Committee sees value in this data collection effort, it views its role as providing recommendations on what data to collect and how, while supporting the Operations and Safety Committee in taking the operational lead on execution with input from other stakeholders as needed.

Next steps:

The OPTN Contractor will summarize its perspective in a memo to MPSC to help guide further work by the appropriate committees like Operations and Safety.

4. Revise Conditions for Access to the OPTN Computer System

The OPTN Network Operations Oversight Committee (NOOC) wanted to inform DAC about a potential NOOC proposal that would require all OPTN members accessing the computer system to execute a data use agreement and report privacy breaches.

Data summary:

The purpose is to require OPTN membership as a condition of access to the OPTN Computer System and reduce potential barriers to OPTN business membership. As well as limit reasons for access to the OPTN Computer System to facilitating organ transplantation, fulfilling OPTN Obligations, and Quality Assurance/Performance Improvement efforts. This would require all members who access the OPTN Computer System to execute a Data Use Agreement (DUA) with the OPTN. This requires all members with system interconnections to the OPTN Computer System to develop an Interconnection Security Agreement (ISA) with the OPTN. As well as require OPTN business members who access the OPTN Computer System to follow the same information security requirements that apply to other member types. And would require reporting for privacy breaches of OPTN Data.

Makes explicit the reasons allowable for members to access OPTN Data within the OPTN Computer System to reasons outlined in HIPAA/OPTN Final Rule. Removes current reason for granting third-party/business access to the OPTN Computer System for placing organs for purposes other than transplantation. OPTN Data is still requestable through the OPTN Data Request pathway for research and placing organs for purposes other than transplantation.

Requires a DUA for every member organization who accesses the OPTN Computer System. The current timing of the agreement is an annual review and a 45-day completion period. Required by NIST 800-53, the security standard for the OPTN Computer System. Draft template modeled after current OPTN patient identified DUA for research.

DUA Template: Key pieces of information included:

- Destruction of Data at the Completion of Use
- Permitted Uses of Released Data
- Entering or managing candidate, PTR, or recipient data
- Entering or managing deceased or living donor data
- Offering, evaluating, and responding to organ offers
- Providing transportation and logistical support for getting the organ from the donor to the candidate
- QAPI initiatives as defined by HIPAA
- Prohibited Uses of Released Data
- Cannot provide data, deidentified or otherwise, to anyone outside of the Member or their subcontractors
- Cannot use Released Data for any commercial purpose that could have a negative impact on patient welfare
- Cannot use Released Data for research or analysis purposes

Requires an ISA for every member organization that utilizes OPTN Computer System APIs. Approximately 275 members currently utilize at least one API. The timing is a renewal every three years and a 90-day completion period. Required by NIST 800-53, the security standard for the OPTN Computer System. Draft template modeled after standard HHS ISA.

ISA Template: Key pieces of information included:

- Member Connected System Details
- System Description, location, user community, and points of contact
- Topology Drawings
- Data Description
- Purpose of the data exchange
- Description of data and data classification
- Security Controls for the Data Exchange
- Includes formal security plans, Incident Reporting and Response, and Risk Management
- Amendment and Modification Procedures

Current policy requires reporting of security incidents within systems that access/manage access to the OPTN Computer System. There can be some overlap between security incidents and privacy breaches, but privacy breaches can occur independently of security incidents and on systems that don't access the OPTN Computer System. Policy would require reporting of privacy breaches of OPTN Data at a member institution within a certain number of hours of confirmation.

Summary of discussion:

The OPTN Contractor identified that there is a lack of clear definitions distinguishing what constitutes "OPTN data" versus data that belongs to the OPTN member as part of caring for their patients. Determining the implications of OPTN data ownership from primary (e.g., retrieved directly from the OPTN computer system) and secondary sources (e.g., EMR data that was downloaded from the OPTN computer system) is critical before implementing a DUA. Several Committee members expressed concerns that an overly restrictive DUA could hinder academic medical centers from conducting research using the data from within their local EMR. There needs to be a defined pathway for research use that does not violate the DUA. Members raised questions around whether the DUA needs individual physician/staff signatures in addition to the institutional member signature. Having every physician sign could create a significant operational burden. Members recommended that clarification is needed on rules around sharing identified vs de-identified data under the DUA. Some members felt that external donor data collected as part of caring for a transplant recipient should inherently belong to that transplant facility/ recipient, not the OPTN. The proposed 3-year renewal cycle was questioned by multiple members as potentially too frequent given institutional renewal processes. There was agreement that the Data Advisory Committee should provide input on better defining "OPTN data" vs "member data" before the DUA template is finalized. Concerns about violations inadvertently occurring and impacting transplant operations if the DUA is too vague or restrictive. Overall, while stakeholders understand the need for a DUA, the lack of clear data definitions and potential unintended consequences on research and clinical care created apprehension about implementing an overly broad agreement. Getting the Data Advisory Committees perspectives incorporated on data ownership parameters and use cases was seen as important before broader rollout.

Next steps:

Review the Data Advisory Committee feedback with the Network Operations Oversight Committee on 03/29/2024. Continue refining project for a future public comment. Discussion underway about defining OPTN data in OPTN policy. Future consideration for the Data Advisory Committee. Following DUA finalization, Network Operations Oversight Committee will share with the Data Advisory Committee.

5. OPTN Strategic Plan Proposal Follow-up: Data Collection Objective

The Chair and Vice Chair presented on the OPTN Strategic Plan Proposal: Data Collection Objective

Data summary:

As an OPTN Board operating committee, the Data Advisory Committee can help shape the Board's efforts to improve data collection as described in the proposed Strategic Plan. The OPTN Contractor submitted a formal response to the public comment proposal.

OPTN Strategic Plan's Proposed Goals:

- Improve Offer Acceptance Rate: Increase opportunities for transplants for patients in need by enhancing offer acceptance.
- Optimize Organ Use: Maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains.
- Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.

Under proposed goal 'Enhance OPTN Efficiency' are the following objectives

Objective 1: Refine the policy development and implementation process to be more efficient and strategically aligned.

Objective 2: Enhance OPTN data collection: increasing availability of actionable data while reducing member burden.

Metrics:

- Decreased policy development time (Objective 1)
- Decreased policy implementation time (Objective 1)
- Policy alignment with the strategic plan (Objective 1)
- Stakeholder satisfaction in the policy development process (Objective 1)
- Milestone achievement in data optimization (Objective 2)

The discussion was focused on objective 2

Summary of discussion:

Committee members advised that it would be beneficial to establish clear, standardized definitions for critical data elements collected across the various OPTN data collection forms. This will help ensure consistency in data entry across transplant centers. Also, evaluating areas of overlap in data collection by different organ committees to identify ways to standardize the content will be beneficial. Members

advised that it would be ideal to develop a comprehensive training program for individuals responsible for data entry at transplant centers. This could involve online modules, in-person training at conferences, and potentially a certification process. The training should cover data definitions, proper data entry procedures, use of available tools and resources, and the importance of data quality. The members advised to establish a systematic approach to auditing critical data elements regularly, targeting specific fields and data on a consistent basis. As well as explore opportunities to leverage technology and automation for data quality monitoring and auditing processes. The members recommended a need to provide guidance and resources to help transplant centers conduct internal data quality audits and address identified issues. As well as fostering closer collaboration and structured relationships with vendors (e.g., EMRs, EDRs, Laboratory Information Management Systems (LIMS), etc.) to improve data capture and integration processes.

Engage with other registries and organizations to learn best practices and explore potential synergies or shared resources. Involve HRSA (Health Resources and Services Administration) and other relevant stakeholders in discussions around data quality and standards. Clearly communicate the value and importance of high-quality data for accurate risk adjustment, organ allocation, and overall system performance. Explore potential incentives or recognition programs for transplant centers that demonstrate excellence in data quality and adherence to standards. Evaluate the need for dedicated OPTN committee resources focused on monitoring and ensuring compliance with data quality standards. Consider updates or additions to relevant OPTN policies (e.g., Policy 18) to provide more specific guidance on data quality standards and requirements. By addressing these areas, the Data Advisory Committee can work towards improving the overall quality, consistency, and reliability of the data collected within the OPTN system, ultimately supporting better decision-making, performance evaluation, and patient outcomes.

Next steps:

None discussed.

Accessing Kidney Data and Graft Failure Information

The Data Advisory Committee discussed the importance of data access and sharing between CMS (Centers for Medicare & Medicaid Services) and HRSA (Health Resources and Services Administration) that are impacting the Chronic Renal Transplant Registry (CRTR) and research in kidney transplantation.

Summary of discussion:

The members discussed that historically, CMS provided CRTR with quarterly extracts from the EQRS (End-Stage Renal Disease Quality Reporting System) data, which included important information on graft failure, dialysis, etc. In 2020, CMS changed their data access policies and moved the data to the CDR (Central Data Repository) platform, which has made it challenging for SRTR to access and link this data. There are ongoing challenges in finalizing a data sharing agreement between CMS and HRSA that would govern access to this CMS data for HRSA's contractors like SRTR. While progress is being made, the agreement is not yet finalized. Even with data access, there are concerns about the ability to incorporate key CMS data elements into the OPTN or SRTR standard analytic files made available to the research community due to lack of approval from CMS currently. CMS has proposed policies that would restrict CMS data from leaving their virtual data environment and charge very high fees for researcher access,

which could severely limit health services and outcomes research using this data. There is a need to increase awareness of these data access challenges within the transplant community and coordinate efforts to advocate for continued and expanded data sharing between CMS and HRSA/OPTN, as this data is critical for patient care, policy, identifying disparities, etc. beyond just research purposes.

The Data Advisory Committee is willing to provide expertise and perspectives to support resolving these data sharing issues given their importance for transplantation. Socializing the problem, amplifying it formally, and coordinating advocacy efforts were suggested as potential next steps.

HRSA shared the Information Exchange Agreement (IEA) between HRSA and CMS was under review and was targeted to be finalized in April 2024

Next steps:

None were discussed.

Potential project ideas: DAC priorities, review list of projects, and time for members to discuss ideas:

The Data Advisory Committee discussed potential project ideas which included more information about the Expeditious Task Force's activities around organ non-use.

Data summary:

A presentation was made by Contractor staff leading the non-use effort for the Expeditious Task Force.

Non-Use Pillar One: Donor/Organ Clinical Characteristics Analysis: Dashboard for investigating non-use

- National and OPO-specific results
- Summary statistics, clustering, and adjusted non-use models
- Goal: Collate information, provide results on contemporary cohorts, and make those results accessible

Probability of transplant calculator:

- National and OPO-specific
- Can be used to inform rescue pathway development

The Expeditious Task Force's non-use working group will provide feedback and prioritization of work. Progress: Dashboard development to start ASAP following working group review (3 stage approach).

Non-Use Pillar Two: Aggregated Offer Acceptance Patterns:

- Use Offer Filters model to identify patterns across groups of programs
- Aggregated by OPTN region, by offer acceptance O/Es rankings, by usage of a screening service
- Goal: Identify types of offers that are accepted/not accepted by types of programs
- Starting with kidney
- Collaborate with both non-use and rescue pathway groups. Results may inform definitions of hard-to- place or criteria for rescue pathway.

Progress: Testing preliminary models while designing full study.

Non-Use Pillar Three and Four: Expert Panel Evaluation Simulation and Qualitative/Attitudinal Research

3: Independent group of clinicians review previously non-transplanted organ offers. Which organs could have been used? Which organs legitimately were not viable for transplant? Was CIT a limiting factor?

4: Non-use/non-utilization story – investigating reasons for non-use and non-utilization not captured in OPTN data. What were the reasons for non-use or non-recovery not captured in non-use/disposition codes?

The non-use working group will provide feedback as needed. Progress: Study design is underway.

Summary of discussion:

The Expeditious Task Force has a working group focused specifically on organ non-utilization, with representation from various stakeholders like patients, OPOs, etc. The non-use group has been organized into different "pillars" or focus areas, each with designated leaders. The Vice Chair advised that they were part of Pillar 3, which seems to be focused on examining granular data, identifying gaps in current data capture, and better phenotyping organs that are not being used. Pillar 1 and 2 appear to be focused on reusing and analyzing existing data in real-time as situations evolve. Pillar 4 is open to considering non-utilization across different organ types, not just kidneys. The Data Advisory Committee was invited to have representation in this non-use group, recognizing the data aspects involved. There was discussion around how the findings and recommendations from this group may inform changes to data capture, coding, reporting and provide feedback to entities like the OPTN Contactor on operational data needs. In summary, it is a focused working group looking at the specific issue of organ non-utilization from multiple angles, including enhanced data collection, analysis and applying findings across organ types. The Data Advisory Committee's role would be to provide guidance on the data aspects.

Waitlist Data Enhancements: The Vice Chair highlighted needs for more granular data on reasons for waitlist removals beyond just death. Another member noted potential needs to re-evaluate how waitlist activity data is collected as clinical situations evolve rapidly. The OPO community is already discussing the needs for agile data collection processes for new areas like organ perfusion. There was an openness for Data Advisory Committee to not just respond to other committees' requests, but proactively identify data gaps/needs. The Chair suggested the Data Advisory Committee could take the lead on assessing data needs around emerging areas like ex-vivo perfusion where evidence is lacking. The overall tone supported the Data Advisory playing a central coordinating role in both advocating for data access and driving enhancements to OPTN data collection.

Next steps:

None were discussed.

HHS Directive update: Next steps

The Data Advisory Committee discussed the HHS Directive update.

Data summary:

Directive Updates: Communications:

- DAC feedback materials posted on DAC's OPTN site (At the time of the meeting this was expected to be completed however that has not occurred)
- DAC Chair memo to all OPTN Committee Chairs (At the time of the meeting this was expected to be completed however that has not occurred)
- Develop educational materials for community on Office of Management and Budget (OMB) process and public comment cycle

Directive Updates: OPTN Response to 60-day Federal Register Notice (FRN):

- Staff drafting response based upon workgroup feedback
- First round – DAC Chairs and MPSC workgroup chair
- Second round – review with selected OPTN Committee Chairs (10 committees identified)
- Third round – review with OPTN Presidents
- Last round – review with OPTN Executive Committee and receive approval
- Share with OPTN Committee Chairs and Society points of contact
- Publish on Federal Register and send communication out to the community

Drafted Timeline: HRSA post 60-day FRN, HRSA processes feedback and updates/finalizes new data collection forms. HRSA then publishes 30-day FRN and would need OMB approval.

Summary of discussion:

The Vice Chair raised the importance of ensuring HRSA considers ways for transplant centers to access and benchmark the new pre-waitlist/donor data being collected, not just HRSA having the data internally. A member confirmed that enabling reporting/data access for the community is part of the draft proposal going out for 60-day public comment period. Things like basic reporting needs, solutions for data delivery to centers/vendors, timelines etc. will be covered. There was discussion around having a pilot/phased rollout to work through anticipated implementation challenges before a full rollout.

A member suggested proactively forming a workgroup to prioritize and standardize data collection needs around procurement and donor data elements, given this is an area of importance identified by societies. The Vice Chair noted the Policy Oversight Committee has done cost-effectiveness analyses that could inform prioritizing which data collection policies to approve first.

There were some technical details discussed around data transmission methods like flat files vs APIs initially, and considerations for centers on different EMR platforms. The importance of doing end-to-end testing during a pilot/phase to identify and document implementation challenges was emphasized. Overall, it seems there is support for providing public comment to ensure HRSA enables data access/reporting capabilities for centers along with the expanded data collection requirements. There was also interest in proactive workgroups to prioritize and standardize relevant data needs. And a phased implementation with robust testing was recommended to smooth the rollout process.

Next steps:

- As forms are finalized, updates will be shared
- If additional feedback is needed for pre-waitlist or ventilated referrals, we will discuss reconvening the workgroups or seek input from the DAC members
- Once decisions are made regarding data collection solutions, plans will be shared with DAC for awareness
- DAC Chairs will be involved in reviewing OPTN Response to 60-day FRN
- Drafted timeline will be updated and shared

6. Review 24-month Refusal Code Monitoring report (final monitoring report)

This project was deferred to be discussed at the upcoming April 8, 2024, meeting.

Upcoming Meeting

- April 8, 2024 (Teleconference)
- May 13, 2024 (Teleconference)
- June 10, 2024 (Teleconference)

Attendance

- **Committee Members**
  - Sumit Mohan
  - Jesse Schold
  - Rebecca Baranoff
  - Jamie Bucio
  - Kate Giles
  - Michael Ison
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Meghan Muldoon
  - Hellen Oduor
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Allen Wagner
- **HRSA Representatives**
  - Adrianna Alvarez
- **SRTR Staff**
  - Avery Cook
  - Ajay Israni
  - Jon Snyder
- **UNOS Staff**
  - Asma Ali
  - Lloyd Board
  - Brooke Chenault
  - Viktoria Filatova
  - Richard Hennings
  - Nadine Hoffman
  - Michael Hollister
  - Houlder Hudgins
  - Sevgin Hunt
  - Sara Langham
  - Krissy Laurie
  - Eric Messick
  - Lauren Mooney
  - Laura Schmitt
  - Holly Sobczak
  - Kim Uccellini
  - Divya Yalgoori
  - Anne Zehner
  - Courtney Jett
  - Carlos Martinez
- OTHER
  - Lisa McElroy, incoming DAC Vice-Chair July 2024