OPTN Data Advisory Committee
Meeting Summary
February 18, 2021
Conference Call

Rachel Patzer, Ph.D., Chair
Sumit Mohan, M.D., M.P.H., Vice Chair

Introduction

The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 2/18/2021 to discuss the following agenda items:

1. Public Comment Proposal Review: Data-inclusive projects
2. OPTN Governance Training
3. 2021-2024 OPTN Strategic Plan (Executive) – public comment proposal
4. UNet^{SM} application programming interfaces (APIs) Update
5. Amnesty Recommendations
6. Candidate and Recipient Deaths During COVID

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

1. Public Comment Proposal Review: Data-inclusive projects

The Organ Procurement Organization (OPO) Committee and Heart Transplantation Committee presented on two items currently out for public comment. Members were invited to provide feedback.

Summary of discussion:

Modify the Deceased Donor Registration (DDR) Form (OPO) – Public Comment Proposal

The Chair of the OPO Committee presented the *Modify the Deceased Donor Registration (DDR) Form* proposal currently out for public comment. This proposal intends to update the DDR form in order to promote more consistent and accurate data collection by modifying, removing or relocating data elements, and improve the quality of data by providing OPO staff with better direction and clarity for data entry.

The members discussed the collection of medication administered within 24 hours of cross clamp data. The OPO Committee is considering whether the information collected needs to be more granular but does not want to create unnecessary burden. Currently, this data is being collected as yes, no, or unknown.

The Vice Chair commented that there is a lot of concern in the community about high discard rates and the quality and granularity of the data collected needs to be considered to help address this issue. Pre and post procurement donor management also needs to be considered. Pump perfusion data is creating a gap and work in this field has been lagging in the US.

A member commented that the donor management data collection is very vague. A lot of donor management fluctuates during the course of a patient's case. If the thyroxine (T4) protocol has initiated hours in advance of cross clamp, this data will not be captured within the 24 hours requested by the

form. More guidance around what is considered a medication in terms of donor management would be helpful. The 24-hour data is helpful but a set list would be more beneficial.

The members agreed that more specificity relating to medication would be beneficial. A member commented that the categorization of medication such as anti-hypertensive or vasodilators are too broad. It is possible for some medications to fall into multiple categories. The member commented that more guidance about what medications to list as well as dosing and timing would be helpful. One concern raised was relating to the accuracy of documenting dosages as administration may be one time or ongoing through a drip which is more difficult to capture within an electronic medical record system (EMR).

The OPO Chair commented that the next steps include further refinement following public comment. Following this refinement, the modified proposal will go to the Board of Directors for review.

Heart-Develop Measures for Primary Graft Dysfunction- Request for Feedback

The Chair of the Heart Committee provided a presentation on the *Develop Measures for Primary Graft Dysfunction (PGD) in Hearts* request for feedback currently out for public comment. The feedback received will inform a future data collection proposal that may include the addition of data elements to the Transplant Recipient Registration (TRR) form to identify PGD in heart transplant recipients.

The Vice Chair asked if there has been any consideration about asking programs to report deviations since there are various baseline protocols. The Chair of the Heart Committee commented that collecting data on all transplant recipients would be ideal but is being balanced with considerations around burden. The Vice Chair supports collecting data on all recipients. A member agreed that the data should be collected on all patients, rather than a subset of those identified as being impacted by PGD.

A member supported collecting data on use of support devices. The member commented that collecting inotrope data will be challenging.

A member asked if the International Society for Heart and Lung Transplantation (ISHLT) will provide comment. The Chair of the Heart Committee commented that they have been engaged and have shared the proposal with their members.

2. OPTN Governance Training

UNOS staff provided an overview of how the OPTN's governing structure guides the OPTN policy development process.

Summary of discussion:

The Chair asked if there is anything DAC members can do to better support policy development. UNOS staff commented that members can support by providing detailed feedback when reviewing projects in development. This feedback will help connect the project back to the larger purpose of the OPTN.

3. 2021 – 2024 Strategic Plan Update

UNOS staff provided a presentation on the 2021-2024 Strategic Plan currently out for public comment. The draft of the 2021-2024 OPTN Strategic Plan was developed with feedback from OPTN committee leadership and Board members. The OPTN Strategic Plan prioritizes initiatives and guides high-level decisions and resource allocation for a three-year period.

Summary of discussion:

The Chair commented that she appreciates the work that went into developing the strategic plan and the results. A member agreed that the goals presented are strong, smart, and achievable. The Chair

commented that DAC can uniquely support the goal to increase equity in access to transplant as well as the equitable allocation of organs through data initiatives and acknowledged that equity in access to transplant begins before the waitlist.

4. UNet^{SM} APIs Update

UNOS staff provided an update on the UNet^{SM} (API) effort to integrate UNet^{SM}, electronic health records (EHR), electronic medical records (EMR), and electronic donor record systems to reduce data entry burden.

Summary of discussion:

UNOS staff asked how many transplant programs and OPOs utilize APIs. UNOS staff commented that there are over 100 transplant programs exporting data using Transplant Information Electronic Data Interchange (TIEDI) APIs and 87 have imported data using TIEDI form APIs which is nearly double from last year.

The Chair asked if participants are routinely exporting data using the APIs and if this is reducing data entry burden. UNOS staff commented that transplant programs have seen the APIs reduce their data burden. The export feature is a workflow that enables the importing of data. Before the API was available, coordinators had to manually download a file, log into UNet^{SM}, and enter the data. Coordinators can now use their 3rd party system to import data into TIEDI which reduces personally identifiable information (PII), protected health information (PHI), and file management efforts.

A Health Resources and Services Administration (HRSA) representative commented that the current OPTN contract has a task that requires all official OPTN data to be collected by API by end of contract to reduce burden of data submission. He asked that the DAC monitor the progress of this initiative and provide oversight for the Board of Directors.

The Chair suggested developing regular updates including more details about the specific data elements, implementation barriers members are experiencing, and program characteristics of those who are adopting APIs compared to those that are not.

The Vice Chair commented that as a transplant center trying to implement APIs, this goal of the OPTN is not well known. He asked what the OPTN is doing to encourage participation and what is being done to monitor the quality and quantity of the data being imported. He also asked what is being collected and captured, rather than overwritten, relating to updated Model for End-Stage Liver Disease (MELD) and Pediatric End-Stage Liver Disease (PELD) scores.

UNOS staff commented that the lab data such as MELD are being captured the same way as when normally updating the patient in Waitlist.

The Vice Chair commented that he is not suggesting the digestion of all EHR data but noted that MELD scores are entered less often in Waitlist than calculated in the lab. He asked if the MELD scores are overwritten if the data is streaming and if only the most recent value is kept for allocation purposes. If more granular and historical data is collected, the trajectory of the patient can be better assessed.

UNOS staff commented that the historical values of MELD and PELD are captured in Waitlist. There are audits of this data and there is reporting of how MELD scores change over time. These values are available in Standard Transplant Analysis and Research (STAR) files.

UNOS staff commented that the API associates the MELD/PELD scores with each registration on the waiting list. The calculator features may support workflows and reduce staff burden but may not be

directly feeding the contract task of seamless data exchange. UNOS staff commented that user workflows and frequency of inputting MELD/PELD values does have variation.

A HRSA representative asked how members are trained or supported in updating their workflows. UNOS staff commented what UNOS is providing is the API which is the technology to link UNOS systems to the members' third party software. Any training on third party software is provided by the software vendor. Integration into their workflow is outside of what is being created.

The Ex Officio member commented that each transplant program has a patchwork of software being used and there is not yet a monolithic solution. UNOS staff commented that the APIs act as a bridge for data that reside in the multiple systems. The member commented that there is going to be variation in participation and use. UNOS staff commented that both the transplant community and integrators are involved when developing these API solutions. If the data is not available in the EMR but is needed for Waitlist, there's no need to develop a bridge. Similarly, there is not a need to develop APIs for data that is only collected in UNet^{SM}.

The Ex Officio member commented that when a candidate is due for an update, their labs are updated to keep them on the waiting list but some patients get updated labs more than once a day. An inpatient may have up to 5 MELD score updates submitted in a day. A concern was raised about how to analyze the waitlist data if the amount of data submitted varies between patients.

UNOS staff commented that APIs rely on user action. There are workflows that are based on clinical decisions so when the decision is made to update the data, associated burden is reduced. APIs are intended to reduce burden, but not affect clinical decision-making.

The Ex Officio member commented that the first goal is to facilitate the work of transplant programs to improve patient care and support the work of the OPTN. As these developments are made, it needs to be questioned how the entering of data changes the data itself when used for analytical purposes.

UNOS staff commented that an emerging trend is that transplant hospitals have started developing their own solutions and building custom workflows. This can be attributed to the increase use of business intelligence tools. Integrating with these systems is not a large effort.

A member asked if there is a higher rate of compliance with reporting TIEDI forms for programs using APIs and asked if there are videos or other resources that could be shared to educate transplant programs leadership. UNOS staff commented that tying compliance with API adoption has been considered but acknowledged there are other factors to considered such as a preference for manual entry. UNOS is exploring ways to share the benefits of integration with programs that have not adopted APIs yet.

The Vice Chair commented that there is a need to assess how successfully the APIs are being adopted and whether they are being used and abandoned. Rules for validations that create errors and burden by program size need to be considered. Larger centers may choose not to participate while smaller programs may not have IT resources. Medium sized programs may be most likely to adopt APIs which creates a data hierarchy. UNOS staff commented that they have not identified trends of adoption relating to program size.

The Chair summarized the conversation stating that the DAC has expressed a want for regular updates on API adoption and implementation, more context relating to the workflows and data flow, as well as additional opportunities to dig into details relating to the import and export of data. The DAC is also interested in program characters such as size as it relates to adoption. Once more information is shared, implications of how the data is being used can be assessed by the DAC.

Next steps:

UNOS staff will coordinate regular updates to the DAC with DAC leadership.

5. Amnesty Recommendations

UNOS staff summarized the recommendations relating to ending the relaxed data submission policy provided by the DAC at the previous meeting.

Summary of discussion:

UNOS staff asked if prioritizing older forms should be a requirement or a recommendation. The Chair commented that for quality reporting and other purposes, not having the older forms will have implications first. The Chair commented that she supports providing tools to allow for tracking progress on submission but cannot determine if the submission of the older forms being prioritized should be required.

A member commented that the Program Specific Report (PSR) deadlines for Scientific Registry of Transplant Recipients (SRTR) should be considered. These deadlines close at the end of April and October. The member commented that it will be difficult to meet the April deadline and suggested calling out the specific forms required to allow programs to focus on the ones needed for PSRs.

The Chair commented that the DAC strives for the best data quality and requiring the forms would support this. A member raised a concern about entering the most appropriate lab data for the appropriate forms so incidents such as recording 1-year data on 2-year forms is avoided. UNOS staff commented that there is a status field on the forms where the program can indicate "not done." It is important that there needs to be clear communication to avoid this identified issue.

The Vice Chair commented that the DAC does not want members entering the wrong time point data. Not requiring form submission makes it hard for hospitals to advocate for the data collection. The challenges during the first surge have dissipated and workflows have adjusted. This data is needed to assess the impact of the pandemic.

UNOS staff asked for recommendations around when the data lock should be implemented. The Chair commented that previously the DAC recommended August 1 or 60 days after retrospective collection ends. A member commented that this timeframe may be too short for all of the forms to be submitted retrospectively and suggested basing the timeline off of the PSR deadline in the fall. The members suggested implementing the data lock on August 30 to allow more time for data submission.

A SRTR representative confirmed that prioritizing older forms is a good approach.

The Chair commented that members need to be notified of the timing and that retrospective data collection will be required as soon as possible.

Next steps:

The DAC's recommendations will be shared with the Executive Committee and discussed during the March 1st meeting.

6. Candidate and Recipient Deaths During COVID

UNOS staff provided an overview of waiting list and post-transplant deaths reported during the pandemic. Overall, there was an increase in removals from the waiting list due to death during COVID. The percentage of deaths of candidates on the waiting list due to COVID ranged from 5-20% depending on the region. There was an increase in post-transplant death seen in all regions except 1, 2 and 6. The percentage of post-transplant deaths due to COVID ranged from 10-30% depending on the region.

Summary of discussion:

A member asked if there are primary and secondary causes of death reported. UNOS staff commented that there is only a primary reason for cause of death reported in Waitlist. There may be up to three causes of death reported on the post-transplant forms.

A member asked if COVID should be entered if there are two causes of death, one being COVID, for a candidate on the waiting list. UNOS staff commented that this is a clinical decision. The Vice Chair commented that a standard response should be provided in order to identify all deaths due to COVID consistently. UNOS staff suggested further refining the cause of death field definition by going through the data definition process.

A member asked if the COVID related deaths would be excluded from performance and outcome analysis. A SRTR representative commented that this issue continues to be reviewed.

UNOS staff will continue to monitor and will provide updates to the DAC through presentations or slides. A member suggested stratifying the data by organ type so the percentage of waitlist deaths can be reviewed across organs.

The Vice Chair asked if there are any programs that have not reported deaths during this period. UNOS staff offered to review this and acknowledged that there may be variation or under reporting due to the relaxed data submission policy currently in effect.

Upcoming Meeting

- March 8, 2021

Attendance

- **Committee Members**
  - Alicia Redden
  - Benjamin Schleich
  - Bilal Mahmood
  - Daniel Stanton
  - Farhan Zafar
  - Heather Hickland
  - Krishnaraj Mahendrara
  - Kristine Browning
  - Lauren Kearns
  - Macey Levan
  - Rachel Patzer
  - Sandy Feng
  - Sumit Mohan
- **HRSA Representatives**
  - Adriana Martinez
  - Chris McLaughlin
- **SRTR Staff**
  - Ajay Israni
  - Betram Kasiske
  - Jon Snyder
  - Nick Salkowski
- **UNOS Staff**
  - Courtney Jett
  - Dean Wilson
  - Elizabeth Miller
  - Eric Messick
  - Julia Chipko
  - Keighly Bradbrook
  - Kiana Stewart
  - Kim Uccellini
  - Lauren Mauk
  - Leah Slife
  - Matthew Prentice
  - Peter Sokol
  - Rebecca Murdock
  - Robert Hunter
  - Sara Rose Wells
  - Sarah Konigsburg
  - Sarah Taranto
  - Susan Tlusty
  - Susie Sprinson
  - Nicole Benjamin
- **Other Attendees**
  - Diane Brockmeier
  - Shelley Hall