OPTN Data Advisory Committee
Meeting Summary
March 27, 2020
Conference Call

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Introduction

The Data Advisory Committee (DAC) met via Citrix GoToTrainig teleconference on 03/27/2020 to discuss the following agenda items:

1. Seamless Data Exchange/Application Programming Interfaces (API)
2. Quarter 2 Data Definition Review
3. Refusal Code Project Update
4. Deceased Donor Registration (DDR) Form Review and Process Feedback Update
5. Modify Data Submission Policy Update
6. Update on Programming Vascularized Composite Allograft (VCA) Allocation into UNet
7. Data Collection and COVID-19

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

1. Seamless Data Exchange/APIs

United Network for Organ Sharing (UNOS) staff updated DAC members on the status of this project and reviewed the goals of exchanging data between UNet systems and systems used at transplant centers: (1) reduce data burden, (2) improve data quality, (3) improve security, (4) expedite data sharing, and (5) increase focus on patient care.

Summary of discussion:

A member inquired about the current status of centers reporting through an API as opposed to the web based form. UNOS staff explained that the current percentage of API coverage is the percentage of data elements where API is possible, not the percentage of current functioning.

A member inquired about the current API usage. UNOS staff explained that over 50 transplant centers and over 60% of organ procurement organizations (OPO) are using APIs. Staff emphasized that different transplant centers and programs adopt solutions that are more pertinent based on their data burden.

A member inquired about how API usage was being measured. UNOS staff explained that a center was considered to be using APIs if it was consuming at least one of the API solutions.

A member inquired about the center-level technological burden that may be hindering the adoption of these APIs. In addition to the technological burden, the flexibility of processes at centers was brought into question. UNOS staff did recognize that centers would have to change their practices, but the hope is that centers will benefit from working with UNOS' APIs and that any future changes to data collection will be easier.

Next steps:

A member inquired about the proportion of transplant centers that use EHRs or EMRs capable of sending UNOS messaging. UNOS staff didn't have an answer, but will follow up with this information.

2. Quarter 2 Data Definition Review

UNOS staff presented the reviewed definition for amputee height and weight, which was an estimate of the height and weight of the patient before the amputation.

Summary of discussion:

A member mentioned that a "best estimate" is not really a definition since an estimate can be decided upon differently by different individuals. All members agreed that some sort of standardization is necessary for this definition.

A member suggested linking a calculator to this definition so individuals that input the data can calculate the field and provide accurate data. UNOS staff explained that, historically, external calculators have not been provided in data definitions and that the external link would need to be validated. UNOS staff also mentioned that they had looked at recommended calculations, but felt the calculations weren't from a valid source.

As an alternative to linking an external calculator, a member suggested soliciting the information that is required for the calculation and UNOS could calculate the amputee height and weight.

The DAC did not endorse the reviewed definition for amputee height and weight. Staff will re-evalute the definition approach for this data definition.

3. Refusal Code Project Update

UNOS staff updated DAC on the refusal code project. The purpose of this project is to update the organ offer refusal codes to improve (1) data quality, (2) real-time offer decision making, (3) understanding of organ refusals, and (4) transplant quality reviews.

Summary of discussion:

A member inquired about how UNOS was receiving feedback on these refusal codes and whether this feedback was going to be brought to the DAC in the future. UNOS staff explained that they were looking for more feedback from the DAC, and other committees, since the project wasn't going through public comment.

A member requested UNOS staff to send the results of the 2018 study done on these refusal codes. UNOS staff agreed to send these results and mentioned the study found that a new catch all code didn't emerge with these codes.

Members agreed that it was critical that these new refusal codes are methodologically sound and that DAC participates in the review of the refusal codes. A member emphasized that it's important these codes are appropriate data responses to improve the rigor of the data system.

These were the recommendations that DAC provided on the refusal codes:

- Under disease transmission, it's completely focused on transmitting infectious disease, but doesn't mention malignancy.
- With the categories temporarily medically unsuitable, refuse, or unavailable – where would one list a patient that isn't worked up or ready for transplant yet?
- Would like to see multi-organ transplant and different laterality separated into two refusal codes, maybe a sister or child option.
- The refusal code for organ preservation (pumping/not pumping) should be split into two codes.

- Presentation of refusal codes – for decision making, tiered system would make it easier for the individual inputting the refusal to be more accurate.
- The number and order of refusal codes should also be discussed – studies show 40 as maximum number of selections for individuals to make an accurate decision.

A member inquired about the implementation time of this project. UNOS staff explained that implementation was expected to occur in 2021; however, there wouldn't be data collected until 2022. UNOS staff emphasized that more urgency can be put on this project if DAC would like to prioritize it.

 A member mentioned that the refusal code list is going to need to serve all organs and inquired whether an organ-specific assessment has been done. UNOS staff explained that this was feedback they were still trying to collect.

The DAC endorsed the Refusal Code Project.

Next Steps:
- DAC would like to receive a detailed presentation on the work done thus far with the Refusal Code Project.
- DAC and UNOS support staff to discuss increasing frequency of meetings to accommodate work on this project.

4. Deceased Donor Registration (DDR) Form Review and Process Feedback Update

UNOS staff provided an update to DAC on the progress of the DDR form review. The sections that have been reviewed are clinical information, lifestyle factors, and organ recovery.

Summary of discussion:

A member mentioned that this is a huge project and inquired whether the current review process, which is using an excel spreadsheet to document comments, is the most efficient way to review the DDR.

Members suggested creating smaller workgroups (with members from organ-specific committees) to work on each section of the DDR, dividing the OPO committee into small groups to work on different sections, and hosting a work day for DDR review instead of frequent one hour calls.

Members were in support of hosting a work day to review the DDR.

5. Modify Data Submission Policy Update

UNOS staff presented an update to DAC on the implementation of Modify Data Submission Policy project. An advisory group, including four DAC members, has been formed and has provided feedback on the draft reports.

Summary of discussion:

No discussion.

6. Update on Programming Vascularized Composite Allograft (VCA) Allocation into UNet

UNOS staff introduced DAC to the project proposing to program VCA data collection into UNet. Currently, the VCA committee doesn't anticipate new data collection.

Summary of discussion:

No discussion.

7. Data Collection and COVID-19

UNOS staff presented the Emergency Actions that have been passed to help the transplant community during the COVID-19 crisis. The actions include: maintaining a candidate's status score or wait time, inactive reasons for candidates on the wait list, COVID-19 specific refusal codes, bulk inactivation for kidney candidates, and candidate/recipient cause of death.

Summary of discussion:

A member inquired whether UNOS was still expecting transplant centers to inform everyone on their waitlist that the center will be pausing transplants. UNOS staff explained that UNOS didn't want to nationally suspend the requirements because different centers are in different circumstances. It is understood that New York has difficult circumstances, but UNOS still asks that centers in New York notify patients regarding organ offers because it's important for the patient to be aware of what's happening.

A member voiced that it seems tone deaf for UNOS to expect centers to find the bandwidth to send letters out to other centers and field phone calls during this crisis. UNOS staff explained that, if the transplant center decides not to notify patients, then that's a discussion for another time. UNOS staff emphasized that, when reviewing reasons for not notifying patients, this crisis will be kept in mind.

A member inquired about how useful the bulk inactivation for kidney patients would be if the inactivation is either 100% open or 100% closed. UNOS staff explained that the bulk inactivation allows centers to filter candidates based on preferred qualifications and then creates a pool of the filtered patients who will stay active and a pool of patients who will be set to inactive due to COVID-19 precautions. UNOS staff emphasized that use of this tool does not mean that centers completely inactivate their waitlist.

A member mentioned that Centers for Medicare and Medicaid Services (CMS) requirements would still require centers to notify patients if they became inactive through the bulk inactivation tool. UNOS staff explained that they can't speak to CMS requirements, but it would seem CMS would provide some regulatory relief.

A member emphasized that, during Hurricane Katrina, CMS and UNOS accepted that centers didn't have the bandwidth to follow normal procedures during that natural disaster. The member explained that, when a center can appropriately justify why they made a particular decision or weren't able to do something, common sense typically weighs in.

A member inquired about what degree UNOS would be tracking centers for follow ups that are not completed within specific time frames as a result of the COVID-19 crisis. Another member inquired about the living donor follow up, since there isn't a "not seen" option on the Living Donor Follow up Form. UNOS staff explained that living donor follow up was discussed during the Policy Oversight Committee (POC) meeting. The POC mentioned that most of the living donor follow up information, besides the lab values, could be gotten from a phone call with the donor.

A member inquired about the lack of guidance being given to OPOs regarding change in volume and protections for procurement teams that are travelling. A member suggested that the best practices for OPOs, on the UNOS website, should be instituted.

DAC members agreed that they want all regulations to not be required by UNOS and for UNOS to allow centers to make their best judgement call without fear of getting in trouble. A member mentioned that something "global" would be more appropriate than what UNOS is currently doing.

A member inquired as to why UNOS has not used the CMS Quality Reporting memo as a template for their response. A member voiced that UNOS actions are more reactive than they are proactive, and it seems that UNOS isn't having discussions about worst-case scenarios. UNOS staff emphasized that these discussions were happening.

A member inquired as to whether UNOS has initiated conversation with CMS or Health Resources and Services Administration (HRSA) and whether members are privy to these discussions.

A member inquired about the number of centers that have informed UNOS they are pausing their living donor programs and informed the living donors. UNOS staff was not aware of the number of programs that had inactivated their living donor programs and explained that, when centers put a hold on living donor transplants, they're not inactivating their living donor program because that program is a part of their overall transplant program. UNOS staff also explained that potential recipients of living donors are also listed on the deceased donor waitlist.

UNOS staff emphasized that living donor follow up had been identified as a priority by POC and that Membership and Professional Standards Committee (MPSC) is working on how to address it and send out the necessary guidance.

Next Steps:

Follow up with DAC on any additional information they can provide regarding living donor follow up.

Upcoming Meetings

- April 13, 2020
- May 11, 2020
- June 8, 2020