OPTN Data Advisory Committee
Meeting Summary
September 10, 2024
In-Person Meeting, Detroit, MI

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Introduction

The OPTN Data Advisory Committee met in Detroit, Michigan on 09/10/2024 to discuss the following agenda items:

1. Welcome, reminders, agenda review, and ice-breaker
2. Preview of Data Lock monitoring report
3. Update associated with Annual Data Quality Report topics
4. Committee work: Discuss DAC priorities and make decisions about future project work
5. Breakout sessions – Member ideas and Report back to Committee
6. Informational: Pancreas Islet Disposition Data Directive
7. HHS Directive update: Next steps
8. Committee work: Form revisions: Donor Acceptance Criteria
9. Informational: Middle Eastern and North African persons project and HRSA request
10. Informational overview of NOOC public comment proposal, Revise Conditions for Access to the OPTN Computer System and Committee questions
11. Public comment proposal: Histocompatibility Committee, Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN
12. Updates concerning workgroup activities
13. Public forum
14. Closing remarks

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

1. Welcome, reminders, agenda review, and ice-breaker

The Chair welcomed the members to the meeting and thanked those who made the trip to Detroit. Committee members and other participants introduced themselves and shared their roles. The agenda included policy discussions, data quality reports, and breakout sessions for brainstorming future activities.

2. Preview of Data Lock monitoring report

OPTN contractor staff presented findings from the data lock analysis. The information detailed the number of changes to data reported to and maintained in the OPTN Data System (also known as TIEDI). There was an improvement in form completion rates after implementing policy changes. The data lock feature is being used, with the Transplant Recipient Follow-up (TRF) form being unlocked most frequently. Common reasons for unlocking forms include delayed reporting due to staffing issues and internal auditing results. Members reported difficulties in mapping fields between their internal Electronic Health Records (EHR) and OPTN forms, requiring extra work. The use of Application

Programming Interfaces (APIs) did not significantly improve data quality and sometimes made processes harder.

Summary of discussion:

No decisions were made pertaining to this agenda item.

OPTN contractor staff presented information suggesting timely form completion rates improved after the implementation of the data submission changes to policy 18, also known as the data lock. The data lock feature is being used. The Transplant Recipient Follow-up (TRF) form is being unlocked most frequently.

The Committee had an in-depth discussion about the data lock mechanism and Policy 18. The Committee was reminded of the purpose of the data lock. It was designed to ensure data integrity by preventing changes to submitted data after a certain period. Since implementation, there are frequent unlocking events where data is modified after being locked. The most common reasons for unlocking forms are delayed reporting due to staffing issues and internal auditing results. The OPTN members contacted for more information about their experiences unlocking date included issues with mapping fields between their internal EHR and OPTN forms, which require extra work. API usage did not significantly improve data quality, and some OPTN members found it made their process harder.

Some of the challenges the Committee discussed regarding the data lock included the high volume of unlocks and the reasons programs indicate for unlocking the data. The committee noted a high volume of unlocking events, particularly for forms like the Transplant Recipient Follow-up (TRF) and Transplant Candidate Registration (TCR). They also discussed the reasons data are unlocked**.** The most common reasons for unlocking were delayed reporting due to staffing issues and internal auditing results. The Committee members agreed that this indicates potential issues with initial data submission processes.

A Committee member asked if it is possible to compare the total percentage of forms unlocked by organ compared with the total number of forms for that organ? For example, the kidney forms have a lot of data elements but the heart forms have data fields that are challenging to understand. The member mentioned that when the data elements are unclear it can lead to a lot of unlocking, potentially. The members also asked whether the number of changes identified in the analysis were the results of members entering data that was previously missing or unknown or were members actually changing values of existing data?

Another member asked about the downstream impact of providing extra time to complete the forms? The member asked if there had been a comparison of how soon the forms were being completed overall, and then what was the impact of additional days on the reporting of data? OPTN contractor staff responded that it is a difficult question to answer because there was no prior data by which to compare reporting timelines against.

Other Committee members identified issues associated with electronically transferring the data from their institution to the OPTN Computer System. A member pointed out that if the electronic transfer process fails then the forms have to be unlocked in order to correct any values. Two members talked about how they had large numbers of forms uploaded electronically fail at the same time. Moreover, it was unclear why the failure occurred making it difficult to identify a corrective action plan.

A member said that at the time of its development, the data lock was particularly concerned about the changes involving the TRF and the TCR. Therefore, it would be interesting to know what proportion of the TRFs and TCRs that are due are actually being unlocked. For example, if 30,000 TCRs are due and all of them have to be unlocked that is much more important to know than if 1,000,000 TRFs are due and

50,000 of them have to be unlocked. In addition, the Committee needs to know the relative proportions of individual forms by organ. If the Committee is interested in determining whether forms are being unlocked around the SRTR data review period, the TRF is unlikely to be unlocked during the periods around the PSRs release. The Committee might benefit from knowing more about the unlocking of the TCR and the TRR because those are what drive the risk adjustment models.

The Chair said the next step would be to discuss data lock improvements, and pointed out that there is a later agenda item to discuss data lock improvements as part of the larger discussion of potential projects. The Committee members agreed.

Next steps:

The 24-month monitoring report associated with implementation of the data lock (*Modifying Data Submission Requirements* project) will be emailed to the Committee members so they have more information to help them review the Committee's submissions to the OPTN Board in November.

3. Update associated with Annual Data Quality Report topics

Discussion of this agenda item included an update on DAC's annual deliverables and a preview of the main themes that are identified in the annual data quality report.

Summary of discussion:

No decisions were made pertaining to this agenda item.

The Committee received a preview of parts of the three deliverables that are produced for the OPTN Board and HRSA, and that they will be provided to them in the upcoming months. The deliverables are comprised of an Annual Data Review Report (Review Report), an Annual Data Quality Report (Quality Report), and a presentation by the DAC Chair.

The Review Report is a summary of DAC's work over the past year. The Review Report includes a synopsis of the policy projects affecting OPTN data collection that the Committee reviewed during their first and second check-ins. The report also includes a summary of the DAC sponsored workgroups and monitoring activities this past year.

The Quality Report contains some standard sections, such as data submission timeliness metrics. The data lock metrics, starting last year, are now included as a standard section. Additionally, DAC selects annual themes to highlight. As recommended by the DAC members in their November 2023 presentation to the Board, the draft currently includes a qualitative analysis of data unlocking. The Quality Report also includes feedback from some OPTN members who had a high frequency of changing data after it was locked, something DAC was interested in last year. The report also looks at data inconsistencies involving the dialysis date between the OPTN Data System and CMS provided data.

The third annual deliverable is a report to the OPTN Board of Directors. The DAC Chair delivers the presentation. Starting last November, an additional virtual OPTN Board meeting was scheduled to ensure OPTN committee chairs who are presenting to the Board have enough time to present and answer questions. This year's meeting is scheduled for November 21st. OPTN contractor staff help the DAC Chair outline and develop the presentation.

As part of the update concerning DAC's annual deliverables, the Committee received a preview of the two themes included in the Quality Report. The rest of this section provides a summary of both themes.

Data Lock

Following the presentation describing the number of forms unlocked and the volume of data being changed, potential reasons for the changes were described to the Committee. The reasons were based on conversations OPTN contractor staff had with staff at three transplant hospitals. The hospitals were selected based on their unlocking activity and API use. As previously mentioned, common reasons provided by the hospitals for unlocking forms include delayed reporting due to staffing issues and internal auditing results. The programs also identified issues with mapping fields between internal EHR systems and OPTN forms; thus, requiring extra staff work to ensure data accuracy. It appears that API usage did not significantly improve data quality and sometimes made processes harder.

With knowledge about the unlocking and data changes reasons, the Committee discussed how the data reporting challenges described by the contacted OPTN members could be addressed while at the same time enhancing the data lock functionality to improve the integrity of OPTN data.

The first option the Committee discussed was making the data lock more stringent to improve data quality. This could involve extending the lock period but also requiring more rigorous justification for unlocking. Another option could involve implementing a system to monitor unlocking events and provide feedback to centers to reduce the frequency of these events.

The Committee further refined the idea by identifying forms like the Transplant Candidate Registration (TCR) and Transplant Recipient Registration (TRR) for the more stringent data lock changes because this data collection is more critical to the transplant process. Members agreed that strengthening the requirements for transplant programs to submit timely and accurate data on the TCR and TRR could have a substantial impact on improving overall data quality. The Chair asked that initial steps be taken to create a project form for the Committee to review and revise. The form will eventually be shared with the OPTN Policy Oversight Committee to inform them about resource needs.

Another option Committee members described was the provision of clear definitions and best practices for data collection. It was strongly suggested that the Committee should focus on solidifying definitions for risk criteria, among other clarifications to the definitions either before or as part of establishing a stronger data lock process. Members also said disseminating best practices can lead to improvements and better understanding of why quality data is not submitted on time.

Having DAC closely collaborate with other OPTN committees to improve data stewardship was another suggested option. Enhanced data stewardship could result in all OPTN committees gaining a more comprehensive understanding of the OPTN's data integrity expectations. A closer working relationship with DAC could reduce transplant program concerns about complying with stricter data lock requirements given staffing and other resource constraints.

CMS Data and Dialysis Discrepancies

As a result of CMS privacy policies changes, the OPTN lost access to certain CMS datasets beginning in 2022. This included a lack of access to information about dialysis start dates. The OPTN regained access to the CMS datasets during the spring of 2024 and the information has now been updated through July 1, 2024. The OPTN continues to receive quarterly updates of the data. Furthermore, this data is utilized in a report that is currently available on the data services portal that compares OPTN waitlist candidates, their dialysis status to that CMS dataset, and looks for existing discrepancies.

Based on the available information, there are 6,500 candidates (19.2%) who appear on the OPTN kidney and kidney-pancreas waiting lists as not receiving dialysis treatment, but for whom the CMS data indicates they are receiving dialysis treatment. In addition, there are about 2,300 candidates (3.5%) whose dialysis start dates are different when comparing the OPTN and CMS datasets.

The members said that dialysis start date is the critical piece of data to have correct because it is used when allocating the organs. A member suggested that having the wrong dialysis date has a direct impact on the allocation sequence. The Committee members expressed concern about the differences in dialysis information between the OPTN and CMS datasets. A member said if the OPTN has information identifying a discrepancy between program reported and CMS data, then the OPTN should email the discrepancy information to the program directing it to check on the discrepancy and resolve any errors. It was pointed out that programs are already provided discrepancy information reports on the data services portal. OPTN contractor staff asked for clarification that the DAC members agree that the information should be emailed to each program to ensure the programs are fully aware of their issues and that they need correction. The Committee agreed with that action to make it easier for programs to fix the errors. Members said if informed about specific errors, then they would likely fix the errors immediately. That would be a better circumstance than having to wade through the report to find the error and fix it.

The Chair said that the OPTN should use the CMS dialysis date as the default date because there is no reason to believe it is incorrect and is about as objective as can be obtained. If a program thought the CMS date was incorrect, then the onus would be on the program to submit a challenge or prove that the CMS date is incorrect. The Chair indicated that this was the process prior to CMS no longer providing the information at the beginning of 2022. Transplant program reported information is less likely to be correct than CMS' information. The Chair also noted that when the OPTN no longer had access to the CMS dataset, there was no way to determine how many patients were on dialysis post-transplant because of graft failure. The only way to make that determination is by using programs' self-report of graft failure, which is highly problematic. The Chair asked if the data can be used to supplement the information the same way that had been done for patients returning to dialysis post-kidney transplant? OPTN contractor staff recommended that be included as a project idea for prioritization with the other analyses and work in progress, and it may require the Committee to submit a data request.

Further discussions about how to improve the data lock and how to better use the dialysis information were addressed as part of the next agenda item.

Next steps:

OPTN Contractor staff will continue working with DAC leadership outlining and developing the annual deliverables, as well as sharing draft versions with the Committee members for feedback ahead of submitting the final versions to the OTPN Board and HRSA.

4. Committee work: Discuss DAC priorities and make decisions about future project work

During the Committee's September 28, 2023 in-person meeting, the members identified both the data lock and the dialysis date discrepancies as areas for additional research and reporting by OPTN contractor staff. Findings associated with those subjects were presented to the Committee. In addition, new subject matter was shared with the Committee for consideration as potential project ideas. Following this part of the meeting, the Committee separated into smaller groups to identify other potential project ideas and report those back to the full Committee.

Summary of discussion:

Decision #1: The Committee members agreed to develop a project form that would focus on strengthening the data lock specifically for the TCR and TRR forms.

Decision #2: The Committee members agreed to follow-up on the ideas they generated as part of this discussion and from the breakout discussions and determine which have the most potential for successful Committee projects.

This section provides more details about the Committee's discussion of the identified project ideas. Their discussions included conversations about steps to enhance the data lock as a tool for improving data quality. The Committee also reviewed potential ways to improve the quality of OPTN data that could be accomplished by modifying *OPTN Policy 18: Data Submission Requirements* and *OPTN Policy 19: Data Release*. The Committee also reviewed other potential project ideas.

Data Lock

A member suggested much of the form unlocking could be the result of problems between electronic health records (EHR) and mapping the data elements in a transplant program's EHR to the requirements of the OPTN dataset. The member said there is a lot of unlocking because of mapping issues. The member also said that there might be benefit from DAC working with other OPTN committees to develop data elements and data collection in a way that makes very clear what programs are to report. For instance, eliminating ambiguity might help address mapping issues. Another member agreed about the need for developing discrete and definable data elements that can be mapped. Another member pointed out how difficult it is to get clear definitions from the other OPTN committees about their data collection intentions and how long clarifications can take. The member underscored the importance of creating a better system to get consistent and clear definitions.

Members agreed that the next version of the data lock must establish at the outset that OPTN members are expected to submit data in a timely manner. They also agreed that the next version needs to be more rigid than the current version. The Vice Chair noted that the data lock mirrors other processes that the Committee has discussed today. For example, the data locking doesn't allow feedback to help identify why centers are having challenges with certain data. The Vice Chair also said it sounds like in the next iteration, the Committee should be looking at the problematic variables and trying to determine whether the problems are because the definitions are outdated and/or need to be evolved. As well as answering questions such as, how does the OPTN operationalize this and involve other data sources that can serve to confirm the data that exists? The Vice Chair suggested that in terms of next steps, perhaps the Committee can identify a key set of variables and focus on developing very detailed definitions.

Another member concurred and said that standardizing the definitions is critical. The member cautioned that such a task might not be possible for an OPTN committee that only meets once a month for an hour. That is a huge lift. Perhaps HRSA would be interested in pursuing a holistic data review again. There was agreement around recognizing and addressing problematic data fields, improving clarity, and considering partnerships with other committees.

The Vice Chair recommended picking two forms, the TCR and TRR, and locking them permanently. In case of an extraordinary event, the Committee can create a more, rigid defined list of the reasons for an unlock request. The Committee should probably have more automated checks of data as it is entered – identify ranges of acceptable data so issues can be addressed in parallel. A member asked if locking these forms impacts the patients in their match potential or does it only impact analyses to compare centers. A member said that the waitlist data is being used for allocation, although the TCR is also used. The need for precision is critical there. Not just for quality or risk adjustment – also have to recognize the transplant registry is largest in the world – has given a lot of info and helped move the transplant field forward. Probably the single most critical resource worldwide. It hasn't kept pace, which is part of

the definition problem too. A patient representative added that when you're the patient and waiting – you're not focused on the data being a resource for research, but for helping you get transplanted.

The Chair recommended that the Committee develop a project for creating a more legitimate data lock specifically focused on the TCR and TRR with a proposed timeline and that the focus should be holistic as opposed to focusing on a particular organ. The project should also address clarifying data definitions and communicating best practices. The Committee should develop a process for managing how outlier issues can be adjudicated after the lock is implemented. The Chair added that DAC should partner with other OPTN committees in developing the new data lock. OPTN contractor staff informed the Committee members that a project form will be created documenting the Committee's ideas. The form will be shared with the Committee for feedback and eventually presented to the OPTN Policy Oversight Committee.

Policies 18 and 19

OPTN contractor staff described DAC as being the 'owners' of OPTN Policy 18 and that the Committee can influence what appears in OPTN Policy 19. The Committee can have the largest impact on the requirements of Policy 18 in the near-term. A brief reminder about data management terminology was provided. Contractor staff attempted to clarify which OPTN committees are involved with each aspect of the data management process.

The members agreed that revising Policy 18 is in DAC's interest. The Chair asked for members to submit their recommendations and from that list and today's discussions the Committee would develop a list of the key processes and policy sections that should be modified.

Among the ideas discussed were modifying Policy 18 in a way so DAC can champion data related changes that are timelier in terms of impact, especially given the slow speed and laborious nature by which data-related changes have been made in the past. For example, the perfusion data that has been proposed for collection has taken a long time to develop but the information is very important for current considerations. Other ideas included pursuing third-party data sources to broaden what is captured in the OPTN data registry. Developing and implementing auditing checks of submitted data are also important for ensuring quality. Additionally, it is very important that the data are transparent. Lack of transparency was a criticism NASEM identified, along with others. The OPTN data needs to be available and transparent so OPTN and non-OPTN entities can analysis and evaluate system performance. It was noted that Policy 18 can apply to all components of the OPTN Computer System (both pre- and post-transplant data collection).

There was discussion about establishing the OPTN data registry as a live data registry that reflects current clinical practice and allows for the introduction of relevant clinical variables. The existing reporting system needs improvement, with a focus on supplementing data and auditing centers for discrepancies. A potential solution would be developing a national transplant data standard to improve mapping and eliminate gaps in EHR data. The Committee might also want to consider the value and relevance of ambiguous data points and potentially remove them from the data registry.

It was discussed that there needs to be a holistic approach to tackling these challenges. It involves recognizing and addressing problematic data fields, improving clarity, and considering partnerships with other committees to help improve data quality. The committee needs to prioritize the collection and refinement of critical data elements. The review process for individual forms should be ongoing to remove obsolete fields and incorporate new ones. Such a review should be performed on a regular cadence. OPTN contractor staff suggested that establishing stewardship of the data at the committee level might also be beneficial. This might be something where DAC sets an expectation with an OPTN

committee that "owns" the data detailing what happens if not in compliance, or how to escalate data quality issues, among other considerations.

A member recommended creating a national transplant data standard. Although there are challenges with doing this, there are opportunities outside of the OPTN that could be leveraged to create such a standard, for example in collaboration with Office of the National Coordinator (ONC). For example, with the known mapping issues across forms, if there was a single data standard from ONC, it could eliminate a lot of need for data mapping because the information would be in the right spot already. It would be a multi-year project but could have large benefits.

Different OPTN committees have influence over various aspects of OPTN data management, and the DAC should be a partner in data use and security, along with Network Operations Oversight Committee (NOOC). There is an opportunity for the DAC to have more authority, including approval of minor data definition changes. DAC should take ownership of critical data quality monitoring and reporting to ensure holistic data stewardship. There is a need to expand and adjust the existing framework to clarify policies for data security agreements. The introduction of a data use agreement (DUA) is necessary for managing and controlling data sets. It was noted that a challenge with third party data is that if they are not OPTN members, then the OPTN does not have the same ability to monitor those exchanges or hold the third parties accountable. That is where the DUAs would come in.

Donor Death Data Collection Project

The Committee also discussed donor death data collection as a project idea. The Committee discussed this subject during their March 2024 meeting and with OPO Committee leadership. It should be noted that the cause of death for donors has significant connotations for other OPTN policies – and is important for that reason. As of now, the OPO Committee stated that they do not have the bandwidth to pursue this project; however, it supports the effort. Therefore, a question is whether DAC should pursue this on their own or wait until other committees can be involved?

A member asked if this was something that DAC could refer to another committee to undertake? OPTN contractor staff responded that DAC has not pursued a "referral" before; however, as an operating committee of the OPTN Board, the Committee could consider pursuing this work as a referral. A Committee member asked how DAC might pursue the topic in an expedited manner because every OPTN committee can point to having multiple priorities, but they may not appreciate the implications associated with an issue like this. The Committee discussed whether the death data would be considered 'critical data elements' and if so, does DAC have the leverage to require changes. It was mentioned that if there are disagreements across committees in terms of work prioritization, then a potential path is to request that POC serve as a mediator. The Committee agreed to keep this as a higher priority item and to seek assistance from the OPO committee and other committees in terms of volunteers to support the work.

Other DAC Project Ideas

Other potential projects the Committee might consider were discussed. Particularly, whether to pursue modifications to the use of "Other, specify" as a choice option. Currently, it exists an option within the Refusal Codes, Waitlist Removal Codes, potential transplant recipient (PTR) Decline Codes, and elsewhere. The consensus was to eliminate, or at least reduce, the use of "Other, specify." Members talked about the issues that result from its use and how it is too easy to use as a default choice. Some members recommended developing a feedback loop to help OPTN members consider using more discrete options and for the members to share ideas for discrete options. The Chair suggested that DAC could work to identify the options OPTN members consider meaningful, see that those are added, and then eliminate the "Other" options. Another potential change would be to require ongoing monitoring

of “Other, specify” options, in Policy 18, with the intention of eliminating the option within two years, or some other specified timeframe.

Next steps:

OPTN contractor staff will finalize a list of all project ideas identified by the Committee and provide the list to the members for review and prioritization. Contractor staff will develop a project form for modifying the data lock for selected fields on the TCR and TRR forms for all organ types.

5. Breakout sessions – Member ideas and Report back to Committee

The members broke into three smaller groups and continued their discussion of potential project ideas.

Summary of discussion:

No decisions were made pertaining to this agenda item.

The following ideas were identified by the three breakout groups. A group identified the need for improved data transport and API functionality to reduce manual entry and to ensure that programs aren’t doing the same work repeatedly. Others in this group mentioned the potential to share best practices and standardization ideas among transplant centers in terms of data reporting and procedures. For example, the data services portal has useful information, but it does not necessarily include the best practices that could help program staff improve their circumstances. This could also take the form of education on forms and policy changes to ensure accurate data submission and reduce data lock issues.

Another group identified the biggest challenge as the burden to enter data. The intention and/or hope is to pull data directly from source system vs map and transform and send. Other ideas the group identified included creating a public facing data dictionary. They also mentioned the need for a periodic review for appropriateness of data aligned with current clinical practice. They also discussed how they might evolve the system. This includes revising the OPTN data registry’s scope to focus on pre- and post-transplant events and creating a separate registry for long term follow up data greater than 3 years, which would include functionality to draw from other, non-OPTN data sources. Finally, the group indicated that it hoped to accomplish the following:

- Establish critical data elements and definitions
- Set accountability and improved monitoring

The third group identified the following:

- Improving the data definitions and data mapping
- Eliminating or modifying the collection of data that is not aligned with current practices
- Improving vendor involvement with DAC and how to engage
- Clarification on data sources – understanding intent for collecting data
- Given lack of data quality measures, should we trust the data?
- Need for more education and understanding of the risk adjustment measures

As a result of their discussions, the Committee identified the following as potential project ideas for the future:

- Modifying Process for Changing OPTN Data (Data Lock 2.0)
- Modifying OPTN Data Submission Requirements (Policy 18) and Incorporate Principles of Data Collection

- Modifying OPTN Data Release Requirements (Policy 19)
- Addressing Dialysis Date Discrepancies
- Refining Refusal Code Data Fields and Reduce Usage of "Other, specify" Option
- Refining Waitlist Removal Data Fields and Reduce Usage of "Other, specify" Option
- Refining Decline Codes for PTR Data and Reduce Usage of "Other, specify" Option
- Expediting Implementation of OPTN Data Changes
- Refining Transplant Recipient Follow-up (TRF) Data Fields (or Revise Form?)
- Improving Data Quality by Enhancing API Functionality
- Improving Awareness of Best Practices Involving OPTN Data
- Creating a Public Facing Data Dictionary
- Defining Critical OPTN Data Fields
- Reviewing Cause Mechanism and Circumstances of Death on Deceased Donor Registration
- Accepting the MPSC Referral for Transportation Events
- Establishing Federal Data Acquisition for Linkage Regarding Graft Loss (Kidney)

The Committee members agreed to revisit the ideas after they have completed their Committee work surrounding the annual deliverables to the OPTN Board. At that time, they will consider how best to prioritize the project ideas.

Next steps:

OPTN contractor staff will add additional information to the list of project ideas and share the updated information for Committee consideration as part of a future meeting. The Committee will prioritize the project list based on factors such as impact on data quality, importance to the community, and resource availability during the next 12 months.

6. Informational: Pancreas Islet Disposition Data Directive

OPTN contractor staff provided an overview of the Pancreas Islet Disposition Data Directive and the associated changes being made by the OPTN in response to the directive.

Summary of discussion:

No decisions were made pertaining to this agenda item.

OPTN contractor staff provided an overview of the Pancreas Islet Disposition Data Directive. A CMS memorandum from January 2024 defined transplanted organs to include pancreata used for islet cell research. The Directive being discussed today aims to align OPTN data collection with CMS definitions and improve documentation for pancreas disposition.

As a result, several changes are being made to the OPTN disposition reason codes to align with the CMS definitions. For example, code 510 is being inactivated. Code 510 was previously used for organs recovered for research. Moving forward, it is being replaced by more specific codes. Contractor staff introduced the new, more specific codes:

- 519: Recovered for research and discarded
- 550: Recovered for research and submitted for research
- 517 and 518: These two codes are specific to pancreas. They are used to distinguish between non-islet cell research and islet cell research.

In additional code 508 is being inactivated. The code has been rarely used. It is being replaced by more specific codes for clarity.

OPTN contractor staff provided timeline information about the Directive and work supporting the Directive. On July 1, 2024, HRSA issued the Data Directive. On August 29, 2024, CMS revised their memorandum. Looking ahead, on October 9, 2024, the contractor will complete the revision of the disposition reason codes in the OPTN Computer System. And, on October 10, 2024, reports will be available for OPOs to review their historical data. OPOs will perform a retrospective data clarification by updating data from 2021 and 2022 using the new codes. OPOs will return the clarified data for updating in the OPTN Computer System.

A Committee member asked if there are any concerns that even if it's in the context of islet cells anchors, OPOs might use code 550? The member continued by asking if the new code should explicitly say non-PA, to avoid any misunderstanding? Contractor staff responded that there will be updated help documentation provided for clarification. But perhaps most importantly, the OPTN Computer System will prevent incorrect code usage by restricting which codes are available for selection based on organ type. The OPTN Computer System is coded so that codes 517 and 518 only appear when importing the Deceased Donor Registration (DDR) form or using the Disposition form in the system. The dropdown choices will not include 550 for pancreas or pancreas segments. Likewise, the reverse is true if documenting for other organs, then the codes 517 and 518 will not appear. As a result, the system will prevent that mistake. Detailed documentation will be included in the system help documentation.

A member asked for clarification regarding code 523 and code 531, related to the term exported. OPTN Contractor staff responded that 'exported' means exported outside of the United States.

The discussion concluded with a plan to follow up on specific questions and ensure all changes are clearly communicated and implemented. The focus remains on improving data accuracy and supporting CMS definitions for pancreas islet cell research.

Next steps:

OPTN contractor staff said that next steps involved revising the OPO performance reports using updated data. In addition, the updated data will be shared with SRTR and included in performance reports by early 2025.

7. HHS Directive update: Next steps

OPTN contractor staff provided a brief status update of the HHS data directive (Directive) to identify the data collection for pre-waitlist referral and evaluation events and ventilated patient donor referrals. The Directive also requires the OPTN to develop the mechanisms for collecting this new data.

Summary of discussion:

No decisions were made pertaining to this agenda item.

OPTN contractor staff said that development of a solution to capture the pre-waitlist and ventilated patient data can occur when the 30-day federal register notice (FRN) is published by the Office of Management and Budget (OMB). A member mentioned that it could be problematic if DAC responds to the ventilated patient information when the MPSC's OPO Performance Workgroup has been managing that effort all along as DAC is not in charge. The member added that it seems in everyone's best interest if DAC and the OPO Performance Workgroup can review the proposal before it goes out and identify areas of agreement and disagreement with what both entities think is reasonable or meaningful.

The expectation is that the pre-waitlist data elements will be the same as those DAC provided as feedback to HRSA on January 31, 2024. It is the ventilated patient data elements and collection form that will likely require some revisions. It is acknowledged that a representative of the OPO Performance Workgroup will need to be part of the discussions with DAC. A member asked if HRSA could provide as much time and insight as possible for DAC to perform an appropriate review and to provide an appropriate response. The member asked if there was a reason why HRSA could not share a preview with DAC? HRSA staff indicated they would follow-up on the question and let the Committee Chair know.

DAC will serve as the lead Committee in developing a draft OPTN response to both the 60-day and 30-day FRN postings. DAC will present the draft to the OPTN Executive Committee to review, finalize, and vote on. After it is finalized, the OPTN response will be emailed to HRSA for consideration per the instructions in the FRN.

Next steps:

OPTN contractor staff will continue updating the Committee as new information becomes available. A planning session will be scheduled for the Chairs to plan next steps on drafting the OPTN response to the 60-day FRN.

8. Committee work: Form revisions: Donor Acceptance Criteria

Committee members were asked to review and endorse data elements associated with Donor Acceptance Criteria. The information will be added to the OPTN Waiting List (also known as Waitlist[SM]).

Summary of discussion:

Decision #1: The Committee approved the proposed changes and additions to the Donor Acceptance Criteria

This action item asked the Committee to endorse clarifications related to offer filters language. This represents new language. OPTN Contractor staff will provide a description of the donor acceptance criteria and inform members that the filters are being monitored and should not be used inappropriately to prevent a candidate from receiving an offer. The OPTN Transplant Administrator Committee (TAC) reviewed this new language and provided their approval. In addition, two DAC members reviewed the changes.

Committee members were shown how the new language will appear in the OPTN Waiting List, under the section header of the donor acceptance criteria. The language that was developed says that transplant programs select applicable donor acceptance criteria fields to identify donor characteristics that are suitable for matches for their transplant candidates. The OPTN monitors the fields and if used inappropriately these fields could prevent a candidate from receiving an otherwise appropriate organ offer.

The Chair asked if any of the members are opposed to the changes and there were no comments. As a result, it is understood that the Committee approves the changes.

Next steps:

The changes will be made to the OPTN Waiting List system.

9. Informational: Middle Eastern and North African persons project and HRSA request

To keep the meeting on schedule and get through other agenda items, the Committee agreed to have OPTN contractor staff email the materials about this topic.

Next steps:

OPTN contractor staff emailed the materials to Committee members on 10/19/2024.

10. Informational overview of NOOC public comment proposal, Revise Conditions for Access to the OPTN Computer System and Committee questions

The Committee received an update about the NOOC public comment proposal, *Revise Conditions for Access to the OPTN Computer System*. The update compared what was submitted for public comment from 07/31 – 09/24/2024 versus what was presented to the Committee during the March 2024 in-person meeting.

Summary of discussion:

No decisions were made pertaining to this agenda item.

The NOOC submitted a proposal during the July 31 – September 24, 2024 public comment cycle. The proposal addressed the revised conditions for access to the OPTN Computer System. Based on DAC leadership feedback, it was determined that the Committee probably did not need to hear the full public comment proposal; however, it would be beneficial to hear about what has changed in the proposal. Basically, the Committee received an update about what is out for public comment now versus what was presented to this Committee during the March in-person meeting.

The presenter indicated there are a few different elements comprising the proposal. The proposal requires all members with system interconnections to the OPTN Computer System to develop an Interconnection Security Agreement (ISA) with the OPTN and requires OPTN membership as a condition of access to the computer system. It is also requiring business members who access the computer system to follow the same information security requirements as other members. Therefore, it is strengthening the security elements and ensuring there is some uniformity to the expectations across member organizations. It also limits the reasons for access to the OPTN Computer System to facilitating organ transplantation, fulfilling OPTN obligations, and quality assurance and performance improvement. In terms of what is different from the preview DAC received in March 2024, this version of the proposal does not review the definition of OPTN data or require data use agreements between members and the OPTN. There are ongoing conversations between the NOOC and HRSA on these topics. The NOOC also wants to ensure that DAC, as a collaborator, is looped in on any efforts related to this topic. A definition of OPTN data and use agreements will be addressed in a future proposal. The proposal is available on the OPTN website for review and comment until 09/23/2024.

A Committee member asked if the NOOC deliberately excluded research as a reason for accessing the OPTN Computer System? The member raised the question due to research trials and how they might be addressed. The presenter responded that yes, the NOOC did intentionally restrict research. The presenter added that this fits with the OPTN Final Rule about using patient identified data. The Committee members generally agreed with the proposed changes.

Next steps:

There were no next steps associated with the discussion. However, the NOOC will continue to appraise DAC about new developments.

11. Public comment proposal: Histocompatibility Committee, Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN

The Committee received a presentation from the OPTN Histocompatibility Committee about a proposal that will potentially modify sections of *Policy 18: Data Submission Requirements*.

Summary of discussion:

No decisions were made pertaining to this agenda item.

The Chair of the OPTN Histocompatibility (Histo) Committee presented the proposal. There are three main elements. First the Histo Committee wants to require critical discrepancy reporting through the OPTN patient safety report and has proposed doing that within 24 hours of discovery of a discrepancy. This addresses the fact that right now, it's required to be reported to the OPO, but it is not being caught in the OPTN Computer System while some of them are being caught in the patient safety portal. As a result, there is not a consistent source of data that's useful for making policy or evaluating compliance. The second main element involves updating the definition of critical HLA discrepancies. The Histo Committee wants to make sure the focus is on the things that are medically relevant while adding the use of incorrect specimens as part of the critical discrepancy error. Making sure that if something happens, for example a lab receives an incorrect sample for a cross match, that the event is recorded in a way that can be used to inform future policy. Third, the Histo Committee is seeking to implement a system wide uniform approach to performing this activity.

The Committee agreed that requiring reporting within 24 hours of a transplant center discovering the discrepancy is reasonable. One Committee member suggested implementing a 72-hour reporting period because a 24-hour response time is difficult for transplant centers to meet.

Next steps:

OPTN Contractor staff will develop a formal response for leadership to review and submit to the OPTN website.

12. Updates concerning workgroup activities

DAC has several Committee members serving on other OPTN workgroups. This was an opportunity for those participants to describe the projects they are involved with and share any information about data impacts and/or questions.

Summary of discussion:

No decisions were made pertaining to this agenda item.

DAC members are involved with other OPTN committees' workgroups, including the OPO, Living Donor, and Operations and Safety committees. Workgroup members serve as DAC's eyes and ears regarding what the other OPTN committees are doing when it comes to data collection and importantly data quality. Members also have an opportunity to spread the message about the importance of data quality throughout the development of any other proposal where perhaps they're thinking of other things as their primary changes. The DAC members serving on the Living Donor Committee's workgroup updated

the members about the project. It was noted that the Living Donor Committee is expected to give a presentation as part of the 10/21/2024 DAC Committee meeting.

Next steps:

There were no next steps.

13. Public forum

There were no requests to speak during this part of the meeting.

14. Closing remarks

The meeting concluded with a focus on solidifying definitions for risk criteria, improving data quality, ensuring compliance with updated policies, investigating issues with completing forms, and discussing future work related to data quality and policy management. The Committee also emphasized the importance of transparency, data accuracy, and continuous improvement in data management practices. DAC leadership thanked everyone for their participation during the discussions

Upcoming Meetings (Meetings start at 3:00 pm (ET) unless otherwise noted)

- ~~July 8, 2024~~
- ~~August 12, 2024~~
- September 10, 2024 – In-person meeting, Detroit, MI, 8:00 am – 3:00 pm (ET)
- October 21, 2024
- November 18, 2024
- December 9, 2024
- January 12, 2025
- February 10, 2025
- March 10, 2025
- April 14, 2025
- May 12, 2025
- June 9, 2025

Attendance

- **Committee Members**
  - Jesse Schold
  - Lisa McElroy
  - Sumit Mohan
  - Rebecca Baranoff
  - Kate Giles
  - Paul MacLennan
  - Michael Marvin
  - Nancy McMillan
  - Christine Maxmeister
  - Jennifer Peattie
  - Julie Prigoff
  - Meghan Schaub
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - Adriana Alvarez
- **SRTR Staff**
  - Avery Cook
  - Ajay Israni
- **UNOS Staff**
  - Brooke Chenault
  - Bonnie Felice
  - Cole Fox
  - Michael Hollister
  - Jesse Howell
  - Sevgin Hunt
  - Eric Messick
  - Tatenda Mupfudze
  - Nadine Rogers
  - Laura Schmitt
  - Joann White
- **Other Attendees**
  - Gerald Morris