OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK Meeting Summary

OPTN Data Advisory Committee
Meeting Summary
February 2, 2023
Chicago, IL

Sumit Mohan, MD, PhD, Chair
Jesse Schold, PhD, MStat, MEd, Vice Chair

Introduction

The Data Advisory Committee met in Chicago, IL on 02/02/2023 to discuss the following agenda items:

1. Predictive Analytics for Adult Kidney Offers
2. Review of NASEM Recommendations
3. Update Non-Utilization Reasons in OPTN Computer System
4. Review Organization of Annual Data Quality Report to Board
5. Holistic Data Review Workgroup Update
6. Overview of upcoming Membership & Professional Standards Committee (MPSC) project addressing OPO Metrics
7. Modify Data Submission Policies Project Efforts and Potential Enhancement Ideas for Data Lock
8. New Project Check-In: Histocompatibility Committee, Revise the Donor and Recipient Histocompatibility Forms
9. New Project Check-In: Histocompatibility Committee, Remove the Kidney Candidate CPRA >98% Additional Data Collection
10. Public Comment Review: Network Operations Oversight Committee, Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements
11. Project Prioritization and Open Discussion

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

1. Predictive Analytics for Adult Kidney Offers

OPTN Contractor Staff presented on the recently implemented project on predictive analytics for adult kidney offers, a new decision-making support tool available within the OPTN Donor Data and Matching System.

Summary of discussion:

The goals of the Predictive Analytics project included:

- Aims to increase offer acceptance and kidney utilization, to better honor the gift of life
- Shows transplant teams the potential impact on a patient when accepting or declining an organ offer by using cutting-edge statistical modeling
- Displays a predicted Time-to-next-offer and gives a mortality prediction over that time
- Built on a highly secure, reliable technology foundation
- Monitored by an advisory group and regularly updated by researchers with community feedback
- Available now for adult kidney offers

This was a collaboration between the OPTN and Accenture Federal Services that was beta and pilot tested between December 2021-2022.

The DAC also reviewed the sources of the data being used for the modeling.

A Committee member stated that this is very useful information and asked if the time to next offer model takes regions into account. The presenter stated that the transplant hospital location is included and they would follow up on regions. The member asked if the predictive analytics could be expanded to other organs, and the presenter responded that the project team is collecting information on how to apply the models to other organs such as adult heart.

A member asked about duplicative variables for CPRA and dialysis time being used for candidate likelihood of death and time to next offer. The presenter mentioned that the difference is based on the status at time of listing versus at time of offer, and that these variables can change over time.

A member of the Committee asked how small hospitals were defined, and asked if there would be a phase to include pediatric populations. The presenter will follow up on the definition of small hospital, and explained that for pediatric patients the group was concerned about small data sets and providing realistic outcomes for decision making so they weren't sure if it would be feasible to incorporate pediatric hospitals.

One member asked about the likelihood of death increasing with serum albumin >3.5 g/dL, and stated that they thought the likelihood of death increased with low albumin levels, not high albumin levels. They also asked why the cutoff for rank on the match run was selected as 1500, and asked how offer filters interacted with the model. The presenter stated they would look into the serum albumin, and that the models need to be periodically recalibrated and that they will likely need to be recalibrated as offer filters become more widely used. The member stated that the challenge is that the people are too optimistic about when the next offer would come, and that if the model averages it out and doesn't' consider bypasses it could increase declines. The member recommended the model err on the less optimistic side and stated that this model may be way too optimistic. The presenter stated that they have heard the feedback and that they currently show the 50% interval in the model, and that in the effort to be transparent people may be focusing on the glass half full. The member stated that if someone needs a better organ or thinks they will get another offer in a reasonable amount of time that may be misleading.

One member suggested adding blood type O to the models, and asked if the model was built on all offers in the system or only those that were utilized. The presenter stated that he was fairly certain that organs that weren't transplanted weren't included in the model, but that he would follow up. The member stated that the model should include all offers and not just organs that were transplanted.

Next steps:

OPTN Contractor staff will follow up on answers to the committee's questions.

2. Review of NASEM Recommendations

OPTN Contractor staff reviewed National Academies of Sciences, Engineering, and Medicine (NASEM) recommendations from their report on "Realizing the Promise of Equity in the Organ Transplantation System" (2022) with the committee.

Summary of discussion:

NASEM recommendations fell into three major groupings:

- Improve equity

- Use more donated organs
- Improve the system and system performance

One member stated that the largest related priority is work in gathering data on patients in the initial evaluation period, pre-listing. The member stated that a lot of disparities arise in the pre-listing period, and the transplant system extends far beyond just the waiting list and onwards. Another member stated that this is important for equity, and relevant to all organ types. The member expressed frustration with this project proposed by DAC not being able to move forward because of regulatory issues and those issue not already being resolved. An OPTN Contractor staff member stated that there may be authority for the project with a referral from the Secretary of Health and Human Services. Another Committee member stated that CMS is trying to collect this information from dialysis centers, but that data is limited to kidneys, and that transplant programs have the needed data in their electronic medical records (EMRs). The member stated that about half of patients referred don’t get listed, and that the data behind this is important. A member of HRSA stated that HRSA is doing legal review and this is on top of the priority list. A member of the committee asked if HRSA is working with CMS to make sure there isn’t duplicative data collection, or similar data collection implemented in different ways. The member of HRSA stated that they are involved with CMS. One member asked where they go from here with the data collection pre-waiting list, and what resources are available to work on it? What data forms should this data be collected on? The member added that this would likely be a heavy lift with new data collection, and they would require other committees’ involvement because of the clinical characteristics.

A Committee member commented that efficiency in the system should be a higher priority. He commented that burden on transplant centers has been ignored and workloads are too high for transplant center staff, and the goals of allocation changes haven’t been worth the effort. He commented that efficiency should be the top priority and everything else should be below it. The member commented that transplant programs should not be responsible for the waitlist mortality of a kidney transplant program, and that people getting lost in the system should be a lower priority. He stated that CMS should look at dialysis units for referrals. Another member stated that it’s down to a balance between equity and efficiency. Another member agreed and stated that right now it’s a challenge because there’s no transparency in the system, so patients aren’t able to make informed decisions and don’t have the data to do so. He stated that it could be a fantastically efficient system with great outcomes if we cherry pick organs and patients on the waiting list, and result in a low waiting list mortality. Another member stated that application programming interfaces (APIs) can help reduce burden with data entry through use of discrete data fields. One member stated that race and ethnicity data are variable and inconsistent within the system. They asked how we could define this, as transplant race/ethnicity is different from the standard. Another member stated that it’s challenging to collect the data but that the committee should focus on how and what is the most important. The original member commented that APIs are great but that not everybody has them and implementing them takes money. Another member stated that the OPTN should work with vendors. The original member stated that HRSA and CMS should mandate standardized EMRs so APIs are more interoperable. Another member stated that the OPTN should make that recommendation, especially as CMS is looking at interoperability.

A representative from SRTR stated that collecting this data was also a recommendation from the SRTR consensus conference. A Committee member asked if there is data on the burden to collect the data. One member stated that the data exists, and most transplant centers know about all of the patients that have been referred. Another member stated that there is pilot data for 30 centers and the data pull takes about an hour or two and once completed it can be repeated easily. Another member stated that it would be helpful to see in a OPTN staffing survey, and that they submitted data to the pilot and it was not easy. They stated that the burden is different for research versus medical evaluation, and that working with the vendors will make it easier.

One member mentioned that the Office of Management and Budget (OMB) released something on race and ethnicity. The member also mentioned that socioeconomic disparity drives inequity, and having better information proxies would be useful in evaluating equity. Right now the information proxies are insurance and zip codes, and more granular demographic information like a seven digit zip code or specific information about social support and economic fluency would be helpful.

An OPTN Contractor staff member stated that the OPTN is working to get OMB approval for all forms, and examining data burden and gotten information from the Transplant Administrators and Transplant Coordinators Committees. In addition, the OPTN will be standardizing race/ethnicity data definitions with the OMB rule.

One member asked if the OPTN collects information on time of referral to cross clamp, as they heard that case time has increased from 24 hours to two to three days, causing staffing issues, and the OPTN should look at those times. Another member stated that there is cross clamp time information, but that otherwise that should be the type of operational data to try to capture. A member stated that they think there has been inefficiency in the system due to the recent changes in the Kidney Allocation System (KAS). The member stated that they think continuous distribution is taking up all of the resources, and that geographic inequity was the least important form of inequity and probably more of a function of transplant center behavior than disparities in organ supply.

One member stated that an idea related to the increased use of organs would be on increasing use of less ideal organs, with expedited offer models for all organs. The member stated that they can't get through the list to get to the right offers and that electronic offers have made that more difficult. They stated that data on perfusion would be helpful, but that reimbursement can be an issue due to the cost of perfusion. Another member stated that there previously was a pilot for expedited kidney offers that wasn't successful that the committee may be able to see in the future, but that perfusion of organs may be outside of the scope, but the lack of data is an issue. The original member stated that exhausting all of the lists while placing marginal organs impacts the placement of other organs. The other member stated that the committee could look at what operational data currently exists and how to use it.

One member stated that the OPTN can't track organs routinely, and that if inefficiencies were the top priority there may be more organs utilized and fewer discards. One member brought up the potential to time stamp an organ at initial offer, decline, and eventual placement, to try to reduce discards.

Committee members provided ideas for additional work they would like around the three main recommendations found in the NASEM report.

Use More Donated Organs

- The use of Donation after Cardiac Death (DCD) organs, and to consider opportunities to collect data about the broader net of all potential donors
- Determine why organs are not being utilized and identify ways to improve the system to increase utilization

Improve system and system performance

- Additional research on OPO systems – different standards than TXCs. To provide interoperability

there needs to be standardization of the measures/standards, and look at the process to design and build the systems. What is the best path forward to build the transfer of information. DAC's standardized data review checklist is intended to force consideration of standards early in the project process
- The use of time stamps in the OPTN Computer System
- The use of "marginal" organs and the impact the use has on the entire system. For example, is it leading to greater non-utilization of all organs?

Next steps:

The Committee members' primary recommendations addressed the following:
- Standardization of data collected by the OPTN
- Initiate collection of pre-waitlist data and information
- Greater collaboration with HRSA, CMS, EMR vendors, and other groups to improve data standardization and data quality
- Consider opportunities to collect additional data, such as information about perfusion.

3. Update Non-Utilization Reasons in OPTN Computer System

The Committee discussed a potential project to update non-utilization reasons in the OPTN computer system. This project would seek to improve data collection regarding reasons for organ non-utilization and identify methods to increase organ utilization.

Summary of discussion:

A member asked if qualifier data, such as free text from the 717 refusal code, could be analyzed to help develop more definitive codes. The member stated that reviewing free text data from transplant programs may be helpful. Staff stated this will be available to the Committee. Staff stated that the Committee should consider refusal codes and non-utilization codes separately. The Vice Chair urged the Committee to work towards eliminating free text fields due to the difficult nature of analyzing data and trends from those type of data elements.

The Chair noted that while refusal codes and non-utilization codes are separate, they are correlated. The Chair explained that if there are large discordances between what is reported a non-utilization code and what the predominant refusal code is, then there may be informative information to analyze in that discordance.

Another member stated that there may be too much focus on programs and outcome performance metrics and not enough focus on the patients. A member noted that the system processes are important for patients.

Another member stated that the transplant community should be reviewing what organs should not be utilized. The member explained that one way to reduce non-utilization rates is to stop recovering organ that should not be utilized. The Chair responded that the non-utilization rate will never be zero, and it should not ever be zero. The Chair stated the Committee should focus on determining what data is needed to answer these questions.

The Vice Chair stated that if the Committee focuses on patient-centric data collection, then it is necessary to consider the populations would do not have access to the waitlist or access to transplant.

The Vice Chair suggested that OPOs should have the opportunity to indicate more than one code to describe why an organ was not utilized at the transplant program level, as it is often a combination of factors.

A member stated that data could be used to suggest certain characteristics of deceased donors that should be excluded from the non-utilization metric.

Another member suggested a data report should include non-utilization reasons by DCD and DBD.

The Committee requested more information about the potential for obtaining OPTN data and analyses regarding the following:

- Expanding recent analysis from liver and kidney to other organs
- Revise and update data through end of 2022
- Examine in more detail the text entered in “other, specify” free text fields for non-utilization reasons
- Time and geographic trends in non-utilization reasons
- Comparison of refusal codes and non-utilization reasons
- Trends related to policy changes, such as KAS and KAS 250 or shortened timeframe for organ acceptance
- Comparison of non-utilization reasons between one kidney not utilized and two kidneys not utilized
- Timestamp data on entry of non-utilization reasons
- Stratify non-utilization reasons by high non-utilization rates compared to low non-utilization rates
- Non-utilization reason rates by organ procurement organization (blinded)

Next steps:

A data request will be drafted and shared with the group in order to help the Committee address organ non-utilization.

4. Review Organization of Annual Data Quality Report to Board

The Committee discussed potentials to revise the data quality report that is submitted to the OPTN Board of Directors.

Summary of discussion:

The Chair suggested revising the data quality report to ensure that it highlights the importance of the Committee and lends to meaningful conversation with the OPTN Board of Directors. A member suggested that first page of the data quality report should rank the most important key issues. The member added that the data quality report should be disseminated to OPTN committee members in addition to the OPTN Board of Directors. The member suggested that key issues could be highlighted for each OPTN committee.

The Vice Chair stated that the data quality report needs to clearly articulate the importance of OPTN data. The Chair stated that the data quality report should be actionable in order to engage the OPTN Board of Directors. The Chair stated that if the Committee seeks to provide more frequent data quality reports, then they may need to ask for additional resources.

Another member stated that the data quality report should tie in a sense of purpose in order to establish the importance of the Committee’s work.

The Vice Chair suggested creating dashboards to increase transparency and accountability for critical data. The Chair suggested collaborating with SRTR to increase efficiency.

The Chair stated that rate of change of data, and biological plausibility are two issues that could be worked on. The Chair stated that those two issues may be easy opportunities for the OPTN Board of Directors to step in and help.

A member suggested the data quality report could include information about non-utilization data in order to highlight the need for updated data on non-utilization of organs.

Another member suggested the data quality report may inquire how the data is generated to help community members analyze their internal processes. The member explained that there may be a lack of understanding in the community about how data is generated.

Next steps:

The Committee will continue to refine and update the data quality report.

5. Holistic Data Review Workgroup Update

The Committee received an update on the work of the Holistic Data Review Workgroup (Workgroup).

Summary of discussion:

The Director of the OPTN Contractor's Enterprise Data Management (EDM) provided the Committee with an overview of the Workgroup's objectives and purpose. The EDM Director also discussed how the Workgroup is helping address a HRSA contract deliverable related to integrating clinical data standards of ICD and CPT codes into OPTN data and operations.

The Workgroup's purpose is to develop a comprehensive plan to present to the OPTN Executive Committee and eventually the OPTN Board of Directors. The Workgroup established how they would approach a holistic review of OPTN data, categorized broad subject areas of OTPN data and identified which OPTN committees should be responsible for specific areas, data elements, etc. Additionally, the Workgroup considered how best to schedule the reviews with the understanding that such an effort cannot be performed successfully all at once. Because the integration of ICD and CPT codes is similar in scope, it will also be addressed in the comprehensive plan. Updates regarding the Workgroup's activities will be shared as part of DAC's regular Committee meetings. The comprehensive plan will be shared with the OPTN Executive Committee prior to the information being shared with the OPTN Board of Directors in December 2023.

Members were asked to let support staff know if they are interested in participating on the Workgroup and/or if they are aware of other individuals who might be helpful to the Workgroup's activities.

A Workgroup member talked about the two components of their activities, mainly the process work around identifying which OPTN committees should be responsible for certain data subject areas and establishing rules for how they review that data, for example. There is also the standardization component of what the group is doing, but is likely a longer term effort.

The Vice Chair stated that if this work should improve the quality and efficiency of data and allow the Committee to be more strategic about new data elements. It was also noted that historically, the OPTN data collection process has been driven by OPTN committees and as a result has occurred from a somewhat siloed perspective. As a result, there are some inconsistencies and inefficiencies associated with OPTN data. The Workgroup's efforts should help to improve those issues. The Committee clarified that in terms of adopting a standardized terminology, including clinical codes, the Workgroup is not limited to considering ICD and CPT.

The member also discussed the importance of establishing well thought-out data definitions in order for users to effectively use the data. For example, having good data definitions ensures the data are correctly used and its limitations are well understood. Additionally, defining the data well can even lead to the metadata having value to the user community. It also increases the potential to effectively link with other data sources.

A member asked the Committee to think about the best approaches for getting clinicians to provide accurate documentation. For example, where an individual is within the transplant process impacts the clinical codes used to describe the individual, but there may substantial differences in coding at different stages. Trying to interpret notes about clinical conditions is difficult because how and where the information is maintained in the patient record. It is also difficult to program APIs to find the relevant information. The members concurred that there are challenges, but this will be an incremental effort, and that trying to map to an existing data model may make it a little easier to accomplish, but it is still going to be a difficult task. Another benefit of standardizing the data is to take whatever standardized data set is agreed upon to the vendors responsible for the electronic medical records and ask them to work towards it.

Next steps:

The Workgroup will continue working towards development of the comprehensive plan to share with the OPTN Executive Committee and the OPTN Board of Directors.

6. Overview of upcoming Membership & Professional Standards Committee (MPSC) project addressing OPO Metrics

The MPSC provided a very early update on their upcoming work to develop OPO metrics.

Summary of discussion:

The Vice Chair suggested the MPSC collaborate with the DAC to determine other data sources that may be relevant, if the MPSC is looking to develop metrics outside of what CMS has developed.

The Chair requested more information on process measures for out of sequence allocation. The Chair requested out of sequence allocation data be provided to the Committee. The Chair stated that out of sequence allocations have a significant impact on equity as those who receive out of sequence allocation offers are largely older, white men on private insurance. The Chair emphasized that addressing out of sequence allocation should be a focus of MPSC work. Staff stated that MPSC reviews all out of sequence allocations and have found that the majority of out of sequence allocations occur after the OPO has done everything to ensure the organ is utilized. Staff added that due to the increase in out of sequence allocations, the MPSC is discussing this issue further to address the root cause.

Next steps:

The MPSC will continue discussions with the Committee on OPO metrics.

7. Modify Data Submission Policies Project Efforts and Potential Enhancement Ideas for Data Lock

The Committee received a presentation addressing the reasons the Modify Data Submission Policies project was initiated and the decisions the Data Advisory Committee made at the time of the project. An additional presentation was given demonstrating the functionality of some of the tools that were created for OPTN members as part of the project.

Summary of discussion:

During 2019, the Data Advisory Committee worked on a policy proposal to improve data quality concerns related to the deadlines for submitting OPTN required data, and the accuracy of the information being submitted. OPTN member organization had reported there was a lack of clarity around the deadlines for the TIEDI forms. There were also concerns that data values were changed after the deadlines, which impacted the accuracy of the data. The Committee proposed addressing the data quality concerns by modifying the initial submission deadlines associated with the TIEDI data, as well as reducing members' ability to make changes following submission. In December 2019, the OPTN Board of Directors approved the proposed changes. Implementation of the changes was delayed due to the COVID-19 pandemic, and eventually occurred in August 2022.

Among the changes extended due dates for certain information. Submission requirements were extended either 30 days or 60 days, depending on the OPTN data collection instrument. The other major change included limiting OPTN members' ability to change their data after the new submission deadlines were reached. In order to accomplish that goal, the Committee chose to "lock" the data at the time of the submission deadline. The extended deadlines and the lock were intended to ensure members provided accurate data in a timely manner. At the time, the Committee discussed the tradeoffs between accuracy and timeliness that would occur as the result of imposing a lock. For example, on one end of the spectrum preventing a member program from making any changes following the submission deadline would lock-in inaccurate information. On the other hand, allowing members to continue to change data values would not improve accuracy. The Committee chose to implement a data lock, but members were allowed to "unlock" their data to make necessary edits. In order to unlock their data, members were required to indicate the reason for doing so, and also to provide the name of a management level professional at their organization who authorized the changes. DAC would monitor and assess the reasons provided when changes were made, and would report annual to the OPTN Board of Directors the data submission compliance rates, the frequency of data changes, and other relevant information identified by the Committee. The Committee determined these were appropriate initial steps, and that future Data Advisory Committees would revisit the 'strength' of the lock and determine if stricter requirements were necessary.

The next part of the discussion described the Data Lock Dashboard maintained for OPTN members. The Dashboard is available in the data services portal, in the OPTN visual analytics section. Currently, OPTN members can access the data lock dashboard and look at potential data quality issues in the form of validation issues or values that might be outside of 'plausible' ranges for certain information. In addition to seeing its own data, the Dashboard also allows members to compare their information against national benchmarks and trends. In addition, an Unlock Activity tab was added in December 2022 which looks similar to the Data Lock tab. It allows OPTN members to see their unlock activities, and make comparisons to national trends.

A member stated that he was unaware of the existence of the either the Data Lock Dashboard and asked that more information be provided to the OPTN community about the information it provides and the where it can be located. The member went further that potentially re-organizing the Data Services Portal might also be beneficial to the community. Another member asked that a further discussion of the Dashboard and its functionality be added to the agenda of a future monthly Committee meeting. The Committee could also use that time to discuss ways to communicate the Dashboard more broadly to the community. Members also had questions about why a member would need information about their own unlock activities, and wondered whether it was redundant.

The Chair indicated that the current threshold to unlock data is such a low barrier to render the lock almost meaningless. Members should be held accountable for entering data correctly the first time, and members that have large amounts of missing data after the submission deadlines should have emails sent to their medical and surgical directors that highlights the problems with their data quality. As a result, the Committee needs to consider the next steps it wants to take. That would require creation of a new project idea around the proposed changes and then following the policy development process.

Next steps:

The Committee will schedule time as part of a future meeting for another presentation about the Data Lock Dashboard, and consider opportunities to share the information available on the dashboard more broadly with the OPTN members. The Committee will also consider initiating a new project to strengthen the "data lock."

8. New Project Check-In: Histocompatibility Committee, Revise the Donor and Recipient Histocompatibility Forms

Summary of discussion:

The Histocompatibility Committee is initiating a new project involving data collection. As a result, the Committee wanted to preview the collection aspects of the proposal with the Data Advisory Committee and secure DAC's endorsement of the initial activities.

The project serves two main purposes. First, to update the Donor and Recipient Histocompatibility Forms (DHF and RHF, respectively) to be in line with current practice. The forms are data collection instruments completed post-transplant by histocompatibility laboratories. Second, to collect data on virtual crossmatching to inform the community on the utility and success, to both improve candidate/recipient care and evaluate impacts on cold ischemic time and allocation efficiency. The Histocompatibility Committee is still developing what a proposed solution will look like, and as a result wanted to begin a dialogue with the Data Advisory Committee to determine what data elements and/or collection processed need to be updated to ensure the most useful information is obtained. This will likely include the addition of data elements related to virtual cross-matching. The Histocompatibility Committee is likely submitting the proposed project to the OPTN Policy Oversight Committee in March 2023.

The Histocompatibility Committee presenter also asked for potential volunteers to join a Workgroup and provide feedback as the project moves forward. The Committee plans on meeting monthly on the topic starting in March and going through November.

The DAC endorsed the data collection being proposed.

Next steps:

The Data Advisory Committee will look to identify members who can provide support to the project.

9. New Project Check-In: Histocompatibility Committee, Remove the Kidney Candidate CPRA >98% Additional Data Collection

Summary of discussion:

The proposal is to decrease the burden of documentation for CPRA of greater than 98% for kidney candidates receiving allocation priority. The relevant sign-offs would be verified as part of the site survey process. Documentation currently occurs in two data fields on the OPTN Waiting list, and one form that is printed and maintained by the transplant hospital. The requirement was established to ensure members were complying with policy.

The proposal would remove the data collection requirements related to approval of unacceptable antigens for kidney candidates with a CPRA greater than 98%. During the past six years, there have been almost no instances of non-compliance, and those that were found were administrative/clerical. The Histocompatibility Committee no longer feels the data collection is necessary for policy compliance.

The DAC endorsed the data collection being proposed.

Next steps:

The Vice Chair asked about the Committee receiving a future presentation about the site survey process as it pertains to data collection, particularly what information is being reviewed and how those reviews are performed.

10. Public Comment Review: Network Operations Oversight Committee, Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements

Summary of discussion:

The purpose of the proposal is to improve IT security across the system, especially in light of the increased use of malware and ransomware attacks against healthcare providers. The OPTN has been working to be prepared for and to thwart any potential such attacks. These efforts have involved external audits of the OPTN's IT security.

The proposal looks to raise the security level to the member level. The proposal also would require OPTN members to put in place plans for how to react when, and if, their data security is breached and patient-level information is stolen.

Proposal requires security training for all users presented in a way that is not overly onerous. Members must go through a security readiness, attestation, and audit requirements for compliance monitoring. Also implements incident management response requirements, which could include removal of access to the OPTN Computer System until the risk is mitigated. The intention is for members to have planned responses in place ahead of time, so they are not trying to develop the plans while the breach is occurring. The proposal is trying to balance usability and practicality with security.

The Chair stated that the proposed training solution does not appear to be different than what OPTN members are already requiring their staff to complete now. And, if that is the case, then any proposed steps should go above and beyond those that are already requires, Otherwise, it is unlikely to be particularly useful. The proposal may also need to take a closer look at how different levels of access are addressed.

Next steps:

The Committee will develop a formal public comment response and share it the NOOC.

11. Project Prioritization and Open Discussion

Summary of discussion:

The Committee identified multiple ideas for additional consideration. The ideas included the following:

- Collection of pre-transplant data

- Socioeconomic information
- Information exploring potential greater granularity of waitlist removal codes - increase in waitlist removals and a patient centric data point
- Delayed graft function, the information has been collected the same way for decades, not particularly helpful (more granular information needed). The current data collection process impairs the OPTN's ability to identify what causes it
- Perfusion data, more marginal organs and how reperfusion is done. Ties into the efficiency discussion
- Where do marginal organs go – should they really be offered to the first 50 on the list? Fine tune how organs are allocated within OPOs (case times)
- Outcome measures – how do we improve the process. A lot of conversation about TIEDI but does not include operational data that exists that could help us understand the decisions we make.
- Better understanding of the data burden at centers – not sure how to add a few questions to the staffing survey. OTPN staffing survey used by executive leadership to get resources.
- What is the OPTN's communication plan for changes to members and vendors. HepB vaccinations as an example, changes were made but did not come back to the DAC.

<u>Next steps:</u>

Support staff will document the ideas and share them with the Committee.

Upcoming Meetings

- March 13, 2023

Attendance

- **Committee Members**
    - Rebecca Baranoff (virtual)
    - Jamie Bucio
    - Michael Ison
    - Lauren Kearns
    - Macey Levan
    - Paul MacLennan
    - Michael Marvin
    - Meghan Muldoon
    - Bilal Mahmood
    - Christine Maxmeister
    - Rachel Patzer
    - Daniel Stanton (virtual)
    - Farhan Zafar
- **HRSA Representatives**
    - Adriana Martinez
- **SRTR Staff**
    - Ajay Israni
    - Jon Snyder (virtual)
- **UNOS Staff**
    - James Alcorn (virtual)
    - Kristine Althaus (virtual)
    - Laura Cartwright (virtual)
    - Brooke Chenault (virtual)
    - Huong Cunningham (virtual)
    - Michael Ghaffari (virtual)
    - Terri Helfrich (virtual)
    - Nadine Hoffman
    - Sevgin Hunt
    - Robert Hunter
    - Michael Hollister (virtual)
    - Courtney Jett (virtual)
    - Krissy Laurie (virtual)
    - Eric Messick
    - Rebecca Murdock (virtual)
    - Joel Newman (virtual)
    - Karen Satke (virtual)
    - Sharon Shepherd (virtual)
    - Susan Tlusty (virtual)
    - Kim Uccellini
    - Read Urban (virtual)
    - Anne Zehner (virtual)
- **Other Attendees**
    - Colleen Flores (virtual)
    - Edward Hollinger (virtual)
    - Peter Lalli (virtual)