

**OPTN/UNOS Data Advisory Committee
Meeting Summary
December 17, 2014
Conference Call**

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Discussions of the full committee on December 17, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Principles of Data Collection

The UNOS Director of Research (Ryan Ehrensberger) presented an overview of the Principles of Data Collection (PoDC). The PoDC were approved by the Board of Directors in 2006, and are the lens with which the OPTN evaluates any new data elements. The PoDC include:

- Develop transplant, donation, and allocation policies
- Determine if institutional members are complying with policies
- Determine member-specific performance
- Ensure patient safety when no alternative sources of data exist
- Fulfill the requirements of the OPTN Final Rule

Collecting data solely for research purposes is noticeably absent from the PoDC. At the time the PoDC were approved, the Board intentionally struck this element from the PoDC. However, part of DAC's work will be to consider whether the current PoDC are still relevant. DAC members should begin considering:

- The purpose of OPTN data collection
- The categories of data the OPTN should collect
- The types of data the OPTN needs but is not collecting
- The types of data the OPTN is collecting but does not need
- Whether the OPTN should collect data solely for research purposes

Other Significant Items

2. Secure Information Exchange Opportunities

The Chief Technology Officer of UNOS (Alex Tulchinsky) presented a shortened version of a presentation he will provide during the in-person DAC meeting in February. The purpose of the presentation is to share the information that is currently collected by the OPTN, how it's collected, and the secure methods used in the healthcare/transplant community that exist to ensure that shared information is securely kept, exchanged, transferred and collected.

The OPTN currently only collects data that are contracted by HRSA or justified by the PoDC. Proposals to collect new data elements must be distributed for public comment and be approved by the Board of Directors. If proposed elements are not justified by the

PoDC they must still be distributed for public comment and approved by the Board of Directors.

Over the last few months, UNOS has been interviewing OPOs across the country to learn about the data they collect and to understand how the OPOs interface with UNet (the OPTN's secure database) and other electronic medical records (EMRs). UNOS is trying to gain an understanding of the data OPOs collect and how they enter it into UNet directly, or through exporting functionality provided by the EMRs.

Many OPOs expressed concern about the "swivel chair and upload process." OPOs must enter data into at least one database, such as an EMR, and then take manual steps to exchange the data with other databases (such as UNet, or the databases at the labs that also support the work of the OPOs). Rather than exchanging the data automatically, OPOs must engage in manual steps, such as using download/upload and exporting functionality, to transfer data from one system to another.

OPOs hope for more seamless integration between UNet and the EMRs they have already purchased. They want to eliminate the manual steps they must take to transfer data between databases to save time and reduce the burden of data entry. They also requested that UNet's functionality be improved so OPOs could access and/or upload imaging data (and any other data or information that do not currently exist within the EMRs or UNet). Finally, OPOs suggested improving members' ability to use information that is entered into UNet; members enter a lot of data but retrieving the same data for candidates in their own centers is difficult. In summary, the transplant community is not requesting that UNOS create a new tool, it's requesting that UNOS creates ways to interact with tools that already exist.

There are overarching information security guidelines and regulations that govern healthcare databases. NIST 800-53 is a government standard and provides a framework for many databases, not just in the healthcare industry. OWASP is a technology standard, and UNOS policy also provides some guidance regarding information security. HIPAA is a federal law that also provides privacy rules. If UNOS becomes more involved with exchanging healthcare information, it may become considered a Health Care Clearinghouse organization under HIPAA, and be subject to certain standards.

Discussion

DAC members noted that increasing data burden on members in the past has led to the demise of some proposals. They acknowledged that permitting databases to interact seamlessly with each other has the potential to reduce the data burden on OPOs and transplant centers because there will be one less manual step. However, they also acknowledged that new data elements will always pose some additional cost on members because the systems will have to be designed/upgraded to capture additional data.

DAC members also asked whether UNOS is having similar conversations with transplant centers, not just OPOs. UNOS assured DAC members that these conversations are happening with all OPTN members. This presentation was focused on OPO responses because the conversations have been occurring while UNOS is on site at OPOs participating in the TransNet beta test.

Representatives from HRSA stated that "we want this group to develop a vision for a data system for the OPTN for OPOs and transplant centers." DAC members identified two key themes for OPTN data collection: 1) how data are collected; and 2) what data are collected. The "how" and the "what" must both be considered to determine the

breadth of data collection, both for policy-making and for improving models. Some members remarked that “we can’t have a better ‘what’ without having a better ‘how.’”

What Data Are Collected:

In order to determine the data that should be collected in the future, DAC members believe the data currently collected by the OPTN must first be analyzed to determine its relevance. The definitions of these data should also be analyzed to determine if they are defined clearly enough to achieve consistency in data collection. Members suggested performing a systematic review of the current data set to determine how each element is being used (in policy or in a model), whether the element is missing in a significant number of cases, and whether there is confusion or quality concern regarding the element. The efficacy of optional fields should also be considered.

For the future, one DAC member suggested establishing a framework for collecting data in logical clusters that follow the lifespan of a patient.

How Data Are Collected:

One DAC member noted that a problem with current OPTN data collection is that data are collected prospectively. The OPTN cannot determine the usefulness of the data until after the data are collected for ample time. There is a “chicken and egg” problem where the OPTN cannot determine the meaningfulness of the data until after they are collected, and do not know that data are necessary until they are already gone.

One member suggested circumventing this problem by creating partnerships with EMR providers that are developing large data repositories. These databases will collect many data elements on patients as they progress through their disease process. When the OPTN or SRTR identifies an element they may affect policies or models, or if literature identifies a data element that may have such an effect, they can partner with the EMR providers to obtain these data because they will have already been collected. This method would help prevent the OPTN from collecting data that are not ultimately useful, and lessens the data burden on transplant hospitals and OPOs because they will have already entered these data into one database.

Sharing data in this way raises a concern about data quality. If data flows from other databases into the OPTN system, what oversight needs to exist to ensure the data are good data? How can programs be held accountable for their data submission? One DAC member opined that if the data entry burden is reduced, the data quality will increase.

Next Steps:

- SRTR will review data points that have already been vetted through organ-specific committees and through the program-specific report rewrite process and report data elements that are not routinely collected today but reported in literature to demonstrate some effect on transplant policy or modeling
 - During the January teleconference, SRTR will provide a 30-minute presentation regarding the magnitude of this work
 - The presentation will summarize SRTR’s opinion of the utility of existing data collection and look at evidence-based publication for opportunities for other data that may be meaningful
- Rick Hasz, Charlie Alexander and Alex Tulchinsky will request information from AOPO to begin analyzing data elements that influence OPO metrics, and will ask AOPO to provide data it believes may be meaningful
 - Jon Snyder will assist

- Joe Kim will formalize his recommendation to put existing data elements into logical groupings
 - Will contact people that work with EMRs (such as EPIC) to determine how they structure data
 - Alex Tulchinsky and Ian Jamieson will help
 - Will review how Tiedi is currently structured
 - Will review SRTR's presentations regarding current data collection and its interaction with PSRs

Upcoming Meetings

- January 21, 2015 via GoToTraining and teleconference at 4pm Eastern
- February 10, 2015 in-person meeting in Chicago, IL from 9am – 3pm Central