

**OPTN/UNOS Data Advisory Committee
Meeting Summary
February 10, 2015
Chicago, Illinois**

**Charlie Alexander, RN, MSN, MBA, Chair
Joseph Kim, MD, PhD, MHS, FRCPC, Vice Chair**

Discussions of the full committee on February 10, 2015 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. Data Release Policy

The Final Rule requires the OPTN Contractor to release to the public “data needed for bona fide research or analysis purposes,” and to “respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.” The OPTN/UNOS data release policy, which governs the data that may be released to the public and the process for doing so, is more restrictive than the Final Rule: it restricts the release of institution-identified data, even though the Final Rule requires the OPTN to release data to allow the public to assess individual transplant programs, and for other purposes.

The OPTN releases institution-identified data in certain formats, such as aggregate tabulations for fields that are on a list that was previously approved by the Policy Oversight Committee (POC), and STAR files with center and OPO identifiers to researchers who state a research need for the institution identifiers and sign a data use agreement. Researchers receiving STAR files cannot present or publish results that in any way identify institutions.

The POC previously developed a proposal to modify the OPTN/UNOS data release policy to make it less restrictive, but during public comment, commenters expressed concern about potential for misuse of data and potential risks to patient confidentiality, and restrictions on release of institution-identified data were added back to the policy language. Prior to presenting the revised proposal to the Board, the policy was tabled because HRSA expressed that the proposed policy was still too restrictive and not consistent with the Final Rule.

The data release policy has not yet been modified, and therefore is still not consistent with the Final Rule. HRSA affirmed this by stating that the policy provides protections for transplant centers and OPOs that are not afforded by the Final Rule or HIPAA. HRSA explained that the OPTN is still permitted to review every request for data to determine whether it is reasonable or for a “bona fide research purpose,” but cannot continue to have a blanket prohibition on the release of certain data.

During its discussions, DAC identified an additional problem: the SRTR releases center-identified data even though the OPTN does not, so the SRTR's data release policies are not aligned with the OPTN's policies and are contradictory. However, the SRTR's

policies also restrict the release of center-identified data for requests that are not deemed to be “bona fide research,” so the SRTR’s policies are also not consistent with the Final Rule.

One DAC member asked whether the OPTN has an obligation to ensure the data are not skewed or interpreted incorrectly. HRSA explained that the OPTN has no such obligation, but reiterated that the OPTN can nevertheless evaluate each data request to ensure its reasonableness.

Ultimately, DAC determined that the goals of this project should be:

- To make the OPTN/UNOS data release policy consistent with the Final Rule
- To align the OPTN and SRTR data release policies
- To align the OPTN and SRTR data release processes

Additionally, DAC requested that the SRTR make its process for validating OPTN data transparent and available to the public, and that both contractors provide DAC with a flow chart of how data requests are processed.

Next Steps:

- SRTR and OPTN will create a flow diagram of how data requests are processed based on the requestor
- Form a subgroup to draft a policy that covers data release for both the OPTN and SRTR

2. Review of OPTN Dataset: “Developing an Evidence-Based Decision-Making Strategy for OPTN Registry Data Elements

One of DAC’s projects is to review data currently collected in the OPTN database and determine whether it should be retained, modified, or deleted, as well as to identify new data elements that should be collected. The SRTR presented a proposed plan for undertaking this large effort in a methodical and evidenced-based fashion. (Exhibit A)

For new data elements, the SRTR proposes using a “modified PICO approach.” As part of this approach, for each proposed new element the DAC would identify:

- Purpose
- Population
- Prognostic Factor
- Outcome
- Practicality

As for the purpose point, some DAC members stated that “improving program specific reports (PSRs)” is not necessarily sufficient justification, as long as it still costs money to collect new data. It may be necessary to explain the true metric of improvement, such as improvement in the c-statistic of a PSR model. However, members also agreed that this consideration must be balanced with the effect that excluding certain data elements has on transplant program and OPO behavior. For example, some transplant centers may refuse to transplant a candidate with a certain risk factor (that is not collected in the OPTN database) because that risk factor is not adjusted for in the PSR. Additionally, DAC members noted that even a small increase in the predictive ability of the PSRs can have a significant impact on the calibration of the models, so DAC must be very careful in how it evaluates the utility of new data variables.

DAC members were also encouraged to consider the hypothetical: if data entry is no longer a burden and no longer imposes a cost (due to the improved IT infrastructure described below) then does the cost-benefit analysis for collecting these new data change? If there is no additional cost associated with collecting new data elements, then should data be collected as long as data are accurate and justified by a principle of data collection? DAC members also articulated a related concern: the Principles of Data Collection may need to be modified to help justify further data collection.

DAC agreed that the effort should be divided into review of current data elements and review of new data elements. The current data element review may be performed in conjunction with the SRTR PSR model rebuild cycle, because the SRTR rebuilds the PSR for each organ every three years, and in doing so reviews the currently captured data and assesses each element's utility.

For new data elements, SRTR performed a "pilot" to test the practicality of performing a systematic literature search to identify potential new elements suggested in published articles. DAC agreed this is a good starting point for the new data collection aspect of the project.

DAC recognized that this will be a large effort, and considered ways to divide the workload, such as by organ type. It did not yet reach agreement on how to divide the workload. DAC also agreed that this will be an ongoing effort, rather than a one-time review of data elements, and SRTR encouraged DAC to consider aligning the OPTN database review with the SRTR PSR model rebuild (which is based on a 3-year cycle). The DAC also agreed that it will need to reach out to subject matter experts, mostly members on OPTN committees, to help provide insight into the utility of current data elements and suggestions for future data elements. These small working groups should also be staffed by representatives from the UNOS IT department and transplant administrators.

Next Steps:

- SRTR will provide a summary of how the new and current data collection review process may work, and make recommendations to DAC
- DAC will determine which aspects of the project can occur in parallel processes
- DAC members will agree on a consistent message and reach out to other OPTN committees to provide an update on this project
- DAC will form a subcommittee to perform these efforts
- UNOS staff will help design a project plan

3. OPO Metrics

In addition to studying current and future data elements that relate to transplant center performance, DAC will also review OPO measures and metrics. The DAC Chair reached out to the Association of Organ Procurement Organizations (AOPO) to request feedback on the future direction of measures and metrics for OPOs. See exhibits B and C for the request and the response.

AOPO explained that the observed to expected (O:E) methodology used to measure yield is a good metric that is rooted in data, and should be an example for the direction of all future OPO measures and metrics. However, the OPO community has not yet determined how to apply the O:E methodology to other metrics aside from organ yield.

For example, the OPO community is still working to figure out how to come up with a measure of “eligible donors,” which is difficult due to variability amongst OPOs.

(http://www.cihi.ca/web/resource/en/organdonorpotential_2014_en.pdf) AOPO is also trying to develop measures to adjust authorization rates. It is important for the OPO community to learn why families refuse donation, in addition to understanding details about those who donate. The OPO community has discussed supplementing their knowledge with non-OPTN data, such as census data, to bolster their analysis.

AOPO also explained that one challenge for improving OPO metrics is that the current OPO metrics are written into CMS regulations. Changing the regulations is no easy feat. The OPO Community, and perhaps DAC, may help identify data to build a metric that CMS may ultimately be willing to adopt. CMS has expressed willingness to consider changing the outcome measures, but they require help from the community to figure out what the new metrics should be.

The OPTN recently completed a deceased donor potential study (DDPS) to determine whether there are people who do not meet the current definitions of eligibility that may nevertheless be suitable donors. If so, the system may need to be modified to be more risk-tolerant. The report will become public once presented at the March 2015 ACOT meeting. The Canadian Institute for Health Information also recently released a deceased donor potential report), which the DAC Vice Chair shared with the committee. This report might help the US learn how donor potential is being assessed in other jurisdictions.

DAC members noted that the donor yield model is generally good, but might inadvertently introduce a disincentive for identifying new donors because the more donors that are identified, the harder it may be to meet the O:E metric by which the OPOs are measured. However, another member noted that even if new data aren't incorporated into the O:E metrics, the information may nevertheless be helpful to inform the community of certain risks, or dispel perceptions about how certain factors may contribute to risk that in reality are not risky. This concept also applies to the transplant center metrics: even if new data aren't incorporated into PSRs or used to monitor policy, do they nevertheless provide information to the community that may positively influence behavior? If so, is this ample justification for collecting new data?

Next Steps:

- Form a subcommittee
- Reach out to AOPO to provide feedback from this meeting

Other Significant Items

4. Goals of the OPTN/UNOS Data Advisory Committee

DAC members took time to articulate their goals for the output of the DAC. The goals as articulated are listed below:

- Gather data with the least amount of effort and expense required for all parties involved, gathering the right data to meet our goals, and build flexibility into our process to deliver data to our customers for quality improvement assessment
- Integrate with other data sources
- Examine and consider removing data currently collected that aren't used to help address the data burden

- Ease the process for members requesting data they entered into the OPTN dataset
- Create a formal environment to improve the interoperability of data between transplant centers and OPOs, the OPTN, and electronic medical record services to ease the burden of data entry for transplant centers and OPOs
- Develop a process for forming partnerships with large data sources, such as large transplant programs, to address unique data needs and study specific data elements
- Review redundancies in the OPTN data collection process to make the system more efficient
- Clarify the definitions of required data elements

5. Secure Enterprise Solutions

The UNOS Chief Technology Officer and Director of IT Operations provided DAC with a summary of their plans to improve the OPTN/UNOS IT infrastructure for collecting data, storing data, and interacting with external sources of data. UNOS IT has been meeting with customers to understand how they use UNetSM and how they use other electronic medical records (EMR) service providers to learn how to better integrate these systems to lessen the burden of entering data into UNet and retrieving data from UNet. The ultimate goal is to automate data transfers between the OPTN data system and the external data sources.

The proposed solution is to build a “data lake.” A data lake is a data storage entity that can receive data from many different data sources and does not silo the data. External data sources, such as EMRs, can input and retrieve data from the data lake through application program interfaces (APIs). Because the data in the data lake are not divided into categories, users are able to access and organize the data in a personalized way that makes sense for their needs. UNOS’s progress on building the data lake is detailed in Exhibit D.

UNOS IT has been speaking with transplant centers, OPOs and EMRs about piloting the process of using the data lake once ready. IT assured DAC that there are centers and software providers that have expressed willingness to participate in a pilot project. UNOS IT also explained that none of the data lake structure is proprietary, it is open source and simply a place to store raw data. UNOS IT also explained that the revision of DonorNet is a separate but parallel project that has some interdependencies.

DAC members expressed enthusiasm for the data lake concept. Successful implementation of the automated data exchange would lessen the burden of data entry on transplant centers and OPOs and others who interact with the OPTN database, which would in turn reduce the cost of collecting new data elements. Additionally, the data lake will allow transplant centers and OPOs to have access to more data that is not pre-organized, which will help with their decision-making. The data lake will also make it easier to interact with new data sources that cannot currently interact with UNet. The UNOS IT department will keep DAC updated with its progress.

UNOS IT also presented a new data quality improvement project to double verify social security numbers and date of birth information entered into UNet. Currently, programming only requires a single verification of these fields, which leads to incorrect data entry and many staff hours correcting the data after they are entered. UNOS IT identified an easy-to-implement and quick solution of programming a double-verification into UNet. After implementation, users will be required to enter SSN and date of birth

information a second time before they can move on to the next page. This project is scheduled to be implemented in the second quarter of 2015.

One member asked whether IT could program a way for transplant centers and OPOs to edit their own data once entered, rather than requiring UNOS staff to perform this role. UNOS staff explained that the ability to edit data is often related to policy, and that editing data in one field often requires the data in other places to be edited.

Upcoming Meetings

- March 18, 2015: Data Release Subcommittee Meeting
- April 15, 2015: full committee teleconference