

**OPTN/UNOS Data Advisory Committee
Meeting Summary
December 16, 2015
Conference Call**

**Charlie Alexander, Chair
Joe Kim, Vice Chair**

Discussions of the full committee on December 16, 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/>.

Plans for Data Advisory Committee (DAC) Work in 2016

1. DAC's Role in the Policy Development Process

DAC's role in the OPTN policy development process has not yet been codified. UNOS staff reviewed the existing policy development process and determined that DAC should play a significant advisory role for projects that in whole or in part propose collection of additional data elements. There are three discrete steps in the policy development process in which DAC should be involved:

- Project approval: DAC is represented on the Policy Oversight Committee (POC) by a current DAC member. When reviewing new project ideas, the DAC representative on POC should be mindful of any projects that may result in new data collection, and should report to the DAC all new projects that are approved by the POC.
- Evidence Gathering: Based on the recommendations from the DAC's POC member and the committee liaison, DAC will work with committees during the evidence gathering phase to ensure that they properly develop evidentiary support for the data collection aspects of their proposals. In addition, the DAC will also ensure the data proposed for collection meet the Principles of Data Collection and other standards that DAC will establish regarding to ensure data are reproducible, not gameable, and have clear definitions.
- Public Comment Approval: For all proposals sent to the POC for approval for public comment distribution, the DAC will review to ensure that any proposed data elements have the proper evidentiary support and meet the standards established by the DAC.

Next Steps:

- DAC will review the Principles of Data Collection to determine if they require any modification
- DAC will establish a standard of review to ensure that proposed new data elements are reproducible, not gameable, and have clear definitions
- DAC will distribute guidance to the OPTN committees to ensure they are aware of DAC's role in the policy development process

2. OPTN Data Vision Statement

The Health Resources and Services Administration (HRSA) requested that the OPTN create a vision statement to describe the OPTN's plan for data in the future, and to provide a framework for data collection. The vision statement is intended to describe how and why the OPTN collects data, but not be so prescriptive that it restricts the

OPTN's ability to accommodate the evolving technology and philosophies supporting data collection. Staff at UNOS brainstormed the following goals for OPTN data collection:

- Reduce the burden of data collection on members
- Improve integrity in data collection
- Improve timeliness of data collection
- Make data dissemination more timely and meaningful to members

The OPTN Data Vision Statement will not be distributed for public comment as it is not a change to any policies or bylaws and does not create a new burden on OPTN members. Because it is an aspirational document providing a framework for the OPTN, however, it requires Board of Directors approval, and therefore must go through the POC project approval process. The project will be considered by the POC in January 2016. Assuming the project is approved, the next steps are:

- UNOS staff approval
- HRSA and SRTR approval
- DAC approval
- Posting on OPTN website for "broad input"
- Board consideration in June 2016

DAC members agreed with the concept and project plan.

3. Data Submission Problems

The OPTN and SRTR have identified numerous problems related to data submission. Some of the problems are likely related to OPTN data submission policies, and some are probably tied to operational decisions made by the OPTN and SRTR. Staff are compiling a list of all the problems and recommendations for a path forward, and presenting them to the DAC.

SRTR presented one of the problems it identified when it released the new kidney program specific report (PSR) model. SRTR developed the new risk adjustment models to be used for the PSRs based on data reported to the OPTN, and provided a 30 day preview of the new risk adjustment model in September 2014, prior to its roll-out in October 2014. Later analysis comparing the data from the September 2014 analytical file with May 2015 data revealed that the new risk adjustment models, which were developed based on pre-September 2014 data, were no longer well-calibrated because transplant programs changed data during the preview period.

The 30 day preview is an operational decision made by the SRTR to provide transplant programs with the opportunity to review the data elements that are incorporated into the new risk adjustment model. Because transplant programs are permitted to edit data after it has been reported to the OPTN, some programs take the opportunity to update the accuracy and completeness of the data reported to the OPTN. However, this also affects the stability of the data already reported to the OPTN. Accurate data are not only critical to the development of the PSRs, but to policy development and research.

The issue highlighted by the SRTR is just one example of the problems related to current data submission policies and practices. The DAC will review additional problems surrounding data submission on its next teleconference, and will plan a path forward.

Upcoming Meetings

- The Committee meets the third Wednesday of every month at 4pm Eastern.