OPTN/UNOS Data Advisory Committee (DAC)
Meeting Summary
February 17, 2016
Conference Call

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

Discussions of the full committee on February 17, 2016 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. **OPTN Data Vision Statement**

   The Committee received an update on the OPTN Data Vision Statement project. The Policy Oversight Committee (POC) approved the project during its January 2016 meeting, but the project is not officially approved until the Executive Committee votes on it. The next Executive Committee meeting is in March.

2. **Data Submission Policy Project**

   During its December 2015 and January 2016 teleconferences, the DAC discussed various problems related to the current OPTN Data Submission policy (Policy 18) and practices. The DAC agreed on the following problem statement:

   > Current OPTN data submission policies lead to a lack of trust and accuracy in data because of the following problems:
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   > • Lack of singular requirement for timely data submission
   >
   > • Ability for members to change data indefinitely after submission and validation
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   > • Lack of definition regarding when it's appropriate to report data as "missing" "unknown" or "unavailable"

   > The data submission policies also contain outstanding ambiguities identified during the plain language rewrite which could be clarified with this effort.

   The Committee voted unanimously in favor of pursuing this project. The DAC's representative on the POC will present it for approval in March 2016. The DAC plans to send proposed changes to the Data Submission policies out for public comment in January 2017. The Committee agreed to form a subcommittee to focus on this project.

3. **Systematic Process for Reviewing OPTN Data Elements**

   Finally, the DAC discussed the other major effort for 2016. There is no systematic review process for reviewing data elements in OPTN database. The OPTN Database may collect data that are no longer relevant or not collect data critical to evaluating outcomes, and definitions of data are not always clear. Because collection of more data increases the burden on OPTN members, the DAC must play an advisory role for projects that in whole or in part propose collection of additional data elements. Additionally, the DAC can advise how to clarify or potentially remove existing data elements.

The DAC agreed the next steps are to establish a standard of review for evaluating new and eventually existing data elements. After the DAC establishes the standard, it will also enforce it at various stages in the policy development process, including:

- Project approval: During its review of new projects, the DAC's POC representative will flag any new projects that have the potential for additional data collection. The DAC will strategize how to work with or advise the sponsoring committees to ensure the proposed data elements have ample evidentiary support and meet the standard of review.
- Public Comment: The public comment proposal template already includes a section regarding new data collection, but the section will include more details to provide support and explain how the proposed new data meet the standard. The DAC will review these proposals and advise the POC about whether the proposals meet the standard.

The Committee agreed to form a subcommittee to focus on this project. The first meeting of the Data Element Review Subcommittee will occur in lieu of the regularly schedule DAC meeting on March 16, 2016.

Upcoming Meetings

- The Committee meets the third Wednesday of every month at 4pm Eastern. However, the March full committee meeting is cancelled in lieu of the Data Element Review Subcommittee meeting.