

**OPTN/UNOS Data Advisory Committee
Meeting Summary
November 19, 2014
Conference Call**

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

Discussions of the full committee on November 19, 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>.

The Data Advisory Committee (DAC) met via Citrix GoToTraining and teleconference on 11/19/2014 to discuss the following agenda items:

1. Overview of OPTN Data System
2. OPTN/UNOS IT Update for DAC
3. SRTR Technical Advisory Committee (STAC) Recommendations

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

Overview of OPTN Data System

OPTN leadership provided a high-level overview of the history, development, and functionality of the OPTN database for the DAC members.

The OPTN data covers every solid organ transplant in the U.S. from October 1987 to present. There are several systems (DonorNetsm, Tiedi[®], and Waitlist) collectively known as UNetsm.

The authority of the OPTN to collect data arose when Congress passed NOTA (National Organ Transplant Act) in 1984. NOTA's purpose is to address nation's organ donation shortage and improve the organ matching and placement process. NOTA established the Organ Procurement and Transplantation Network (OPTN) to maintain a national registry for organ matching.

Below is a chronological overview of how the OPTN's data system has developed into what it is today:

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|-----------------|---|
| ▪ October 1987 | OPTN data collection began (paper forms) |
| ▪ January 1993 | Electronic data entry required |
| ▪ April 1994 | Introduction of Tiedi [®] |
| ▪ October 1999 | Introduction of UNet sm (Web-based data system) |
| ▪ July 2003 | Introduction of DonorNet sm |
| ▪ June 2006 | OPTN Board approved Data Reduction project |
| ▪ December 2006 | OPTN Board approved Principles of Data Collection (PoDC) |
| ▪ March 2007 | CMS released Conditions of Participation |
| ▪ April 2007 | Requirement for electronic offers in DonorNet sm |
| ▪ 2013 | KPD data collection integrated into UNet sm |
| ▪ July 2014 | VCA data collection begins |

OPTN leadership reminded the committee that one of its tasks will be to review the PoDC and determine if there needs to be changes to the principles and if so, identify those changes.

The primary goal, as handed down by the Board of Directors, of the OPTN database is to improve patient outcomes. The Board of Directors approved five principles in furtherance of the goal of improving patient outcomes. These five principles are referred to as the OPTN Principles of Data Collection. As such, all data collection must be for one of the following purposes:

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

Notably, what is not listed in the PoDC is the data collection for the purposes of research. Data collection for the purposes of research was contested at the time the Board passed the PoDC. Some members believed that OPTN data collection should further research while others believed that OPTN data collection for research is not within the realm of the OPTN's authority and responsibility.

When the Board of Directors passed the PoDC the Board included the following operational statements for data collection in the resolution:

1. The OPTN will only collect data that is contracted by HRSA.
2. Data collected and submitted by Institutional Members to the OPTN may differ in nature and character for specific populations, forming exceptions to Guiding Principles above (e.g. Pediatrics, Living Donors). For these exceptions to the foregoing principles, alternative sources of information must be explored and supported, duplication of existing efforts (e.g. registries) avoided, and sample data collection considered. The need and purpose of any such exceptions must be clearly articulated and subject to Policy Oversight Committee and Board approval, and public comment.
3. All future data requests by OPTN committees must be justified in the context of the above guiding principles, and new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN, and be subject to public comment.

As such, this is the process by which the OPTN operates today. Since the PoDC were approved eight years ago, and there have been changes in the transplant field since then, it is time for the PoDC to be reassessed and updated as needed.

OPTN leadership then went on to expand upon the kind of data the OPTN collects. In the pre-transplant world we start with waiting list candidates.

- When patient listed, the member submits basic patient information that is needed for allocation purposes. Simultaneously, a Transplant Candidate Registration form (TCR) is generated in Tiedi®.
- Waiting list data is updated throughout
- Donor information is entered into DonorNetsm. This is information needed to place the organs available for transplant and includes demographics, testing results, lab results, etc.
- Donor information is fed into match run in order to match a donor with the recipient.

- Potential Transplant Recipient (PTR) data is derived from the match list. Each person on match run list needs either to refuse or accept the organ. If a potential recipient refuses the organ then the member must provide a reason for not accepting the organ (aka refusal reason). Alternatively, the member may bypass a certain number of recipients for an acceptable reason.
- When the organ is accepted the transplant center removes the candidate from the waiting list and a feedback record is generated within the system.
- Once the donor feedback system is complete, another set of forms is generated within Tiedi®
 - OPO responsible for completing the Deceased Donor Registration Form (DDR)
 - Transplant center is responsible for completing the Transplant Registration Form (TRF) and Transplant Recipient Follow-up Forms (TRF), which are due at 6 months and every 12 months post-transplant and until graft failure or death.
 - The recipient and donor histocompatibility donor labs are responsible for completing the respective histocompatibility forms.
 - There is a less complicated process for Living Donor forms and all Living Donor forms are completing at the transplant hospital. Specifically, follow-up forms for Living Donors are only due at 6 months, 1 year, and 2 years post-transplant.

The OPTN gathers the data and collapses it into numerous tables and reports. In addition to the OPTN data, the OPTN supplements the OPTN data with outside data sources. For example, there are several outside sources on death data, and the OPTN supplements with CMS data regarding ESRD. Supplementing the OPTN data leads to an enhanced OPTN data set.

A member asked if there is validation process that occurs after the data is gathered. OPTN leadership explained there is limited verification on site surveys, but most of the data reviewed during site surveys is data associated with allocation and not associated with form-based data.

OPTN/UNOS IT Update for DAC

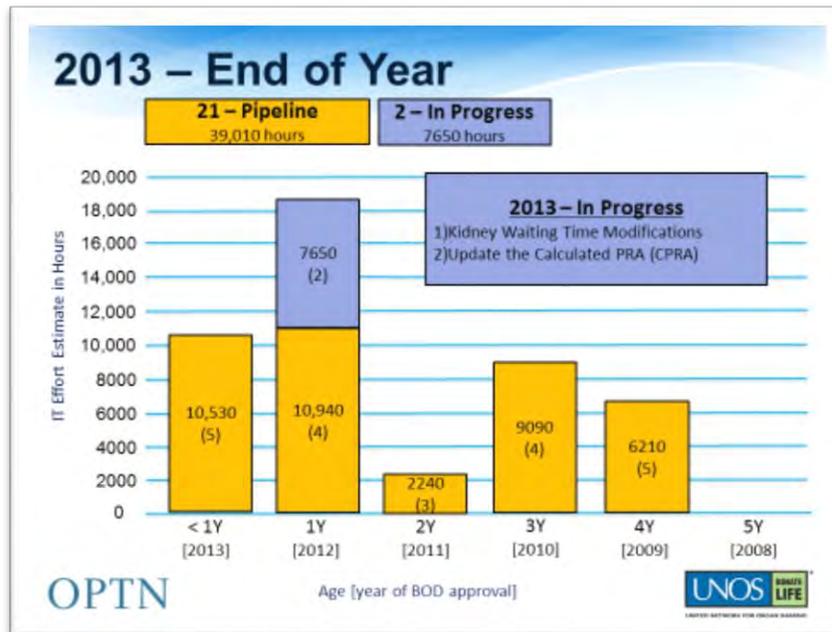
OPTN leadership gave a presentation on the status of the OPTN/UNOS IT department and what that status means for the DAC members.

OPTN leadership showed a diagram of current Board approved projects the IT department is working on and will be working up until the end of 2015. Specifically, the IT department is working to complete the backlog of Board approved projects by the end of 2015. In addition, the IT department has challenged itself to complete all Board approved IT projects from the June 2014 Board approved projects by the end of 2015 as well. The IT departments top priority projects, as decided by the Executive Committee, are:

1. Requiring reporting whether donor screening tests are completed using qualified specimens
2. HLA equivalency tables
3. Potential donor-derived disease transmission reporting
4. Improve vessel disposition reporting

Notably, the current 2015 Projects Timeline does not include the HOPE Act. However, IT leadership has determined where there is capacity to perform the projects associated with implementation of the Hope Act: HOPE Act Prep Work, HOPE Act Living [Donors], and HOPE Act Deceased [Donors].

In order to begin to explain how the IT department knows that it is making progress, OPTN leadership showed the chart below, which represents the number of projects and corresponding number of hours associated with each project as of the end of 2013. OPTN leadership explained that IT's goal is to reduce the historical back-log of progress as well as create capability to simultaneously complete current IT projects.



By the end of 2014, the IT department will have implemented the following seven projects:

1. Kidney waiting time
2. Update CPRA
3. Reorganize hemodynamic data on heart justification form
4. Modify requirements for mandatory HTLV-I/II
5. Patient safety reporting
6. PA/KP Allocation
7. KAS (will be implemented December 4, 2014)

The IT projects that will be in progress at the end of 2014 will be:

1. Ped lung diagnosis – other specify
2. Tiedi® IMB
3. Revise LAS
4. Potential donor derived disease transmission reporting
5. Living liver donor follow-up

Regarding 2015, IT is looking ahead and is aware that the June 2015 Board meeting could produce a double-work load for IT since the June 2015 Board meeting will include proposals from two separate public comment cycles. IT's goal is that by the end of 2015, have the capacity to take on new work.

Regarding the ETT Project – TransNetSM, there are currently eight OPOs and one transplant center who are participating in the project. There will be a voluntary national rollout of the project

from approximately March – June 2015, followed by transplant center beta test and user acceptance. Then the non-voluntary national rollout will occur in the second half of 2015.

The OPTN IT department is actively working to identify ways to better serve the “customers”. OPTN IT representatives have reached out to members to collect information on how members use UNetsm and the associated programs, in order to deliver better products to the members.

Specifically, IT representatives are working with OPOs to identify the extent of the OPOs ability to interact with UNetsm, and identify any challenges OPOs may have with interacting with UNetsm. OPOs frequently use the import/export functionality in order to remove data from the OPO software systems and push the data into the UNetsm database. However, OPOs have indicated there is still manual data entry. As such, OPOs are asking for their software applications that directly communicate with UNetsm, and eliminate any need for manual data entry. OPOs have also identified challenges associated with extracting data from UNetsm.

The current state of technology for the OPTN is analogous to a Gordian knot. This means that a simple change request to the IT structure requires numerous changes throughout the database. As such, a small change may turn into a big effort for the IT department. OPTN leadership is looking to shift the technology to produce modular services that operate independently of each other. This will allow small changes to have a limited impact. OPTN leadership proposed to do this by creating an algorithm layer that houses business logic, and a data layer that houses the database.

Currently, the IT department has an information architecture project underway where IT employees are looking at how the OPTN collects, stores, analyzes, structures, and shares data. This allows the IT department to ask the important questions regarding how to enhance the current information architecture.

SRTR Technical Advisory Committee (STAC) Recommendations

SRTR leadership provided background on the STAC as well as review recommendations the STAC has made to the OPTN Board.

SRTR leadership gave a brief background on the relationships between HRSA, SRTR, and the OPTN. Notably, the SRTR takes its direction mostly from the STAC.

The purpose of the SRTR Technical Advisory Committee (STAC) is to advise the Scientific Registry of Transplant Recipients (SRTR) on:

- Analytic methodologies to support the Organ Procurement and Transplantation Network (OPTN) policy development and evaluation;
- Objectives, study designs, and statistical methods for research projects performed by the SRTR, including risk-adjusted analyses of organ procurement organization and transplant program performance (PSRs);
- Methods used in simulation allocation models (SAMs);
- Requests for patient-identified data files; and
- New areas of research and innovative advances in analytical methodologies that might improve the effectiveness of the SRTR (example: new Bayesian Methodology approach).

Regarding membership, the STAC must have a diverse membership with broad capabilities, where each member brings important and relevant areas of expertise. The STAC includes 8 to

10 voting members with qualifications in the areas of organ procurement, clinical, statistical, and/or epidemiological research related to transplantation, economics, simulation, and analytics for predictive modeling.

The strengths of the OPTN existing data is that it contains a broad set of data elements that spans many years of data. In contrast, the weakness of the OPTN existing data is that, arguably, there is missing data, data quality varies, and important predictors are not collected.

STAC presented a report to the OPTN/UNOS Board of Directors in November 2009. Selected recommendations in this report are as follows:

- Need to determine the resources required to achieve improved predictive ability (increased data collection, cost)
- Review and potentially eliminate subjective variables from risk adjustment models that might be gameable
- Standardization, education, communication and audit of model variable use
 - May improve predictive power
 - Reduce potential for systematic error or gaming
- Missing data has been demonstrated to be a statistically significant factor for some variables
 - Predictable patterns are rare and not consistent across programs
 - However, evaluation of statistically significant missing variable requires further study
- Programs should be expected to review and correct their missing data
- OPTN should develop Program Performance Policies related to missing data
- Review and where appropriate eliminate instances of specific responses (i.e. “unknown”)
- Reinforce OPTN and SRTR education including clear instructions on completing forms
- Review OPTN auditing processes for missing-ness and accuracy of data elements
- New data elements
 - There needs to be a process to review, add or remove data elements, based on pilot studies that demonstrate a contribution to the model
 - A work group including HRSA, OPTN and SRTR should proactively manage this process to improve the model, encourage research, and increase our knowledge of critical factors that contribute to advancing the science and practice of transplantation
 - This data management process needs to be done on a continuous or at a minimum cyclical time

Regarding data quality, data entry and the verification processes need to be uniform across transplant centers.

When the SRTR had a consensus conference on program-specific reports a few years ago, the SRTR released an informal poll to consensus conference participants regarding what data should be included and what data should be excluded. As a result, SRTR leadership recommended that the following additional elements should be included in risk adjustment:

Which additional elements should be included in risk adjustment?

<p>HEART</p> <ul style="list-style-type: none"> •3—Non-transplant deaths •Donor & recipient risk •Recipient requires vent •Repeat sternotomy •VAD prior to transplant •Prior congenital heart surgery •Positive cross-match <p>LUNG</p> <ul style="list-style-type: none"> •PRA, multi-resistant strains •Donor & recipient risk <p>PANCREAS</p> <ul style="list-style-type: none"> •3—Cardiac comorbidities •2—Non-transplant deaths •Donor & recipient risk •Length of time on dialysis prior to listing 	<p>KIDNEY</p> <ul style="list-style-type: none"> •5—Cardiac comorbidities •3—Non-transplant deaths •3—Time on dialysis •2—Pos. X-match; desensitization •2—Donor & recipient risk •Financial stability and compliance hist. •Premature death statistics and genetic diseases in a geographic population <p>LIVER</p> <ul style="list-style-type: none"> • 2—Non-transplant deaths • Cardiac comorbidities • Young age as a separate risk factor • Donor & recipient risk • Months of abstinence • Pediatric: parents' risky behaviors • Time at given MELD score • BMI
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Notably, consensus conference participants suggested that gameable data fields should be excluded. As a result, SRT leadership recommended that the following additional elements should be removed from risk adjustment:

Which additional elements should be removed from risk adjustment?

<p>HEART</p> <ul style="list-style-type: none"> •2—Functional status •Primary insurance type •Ethnicity •Donor gender •Ones that alter risk due to "missing" •Census/educational levels <p>LUNG</p> <ul style="list-style-type: none"> •Functional status •Primary insurance type •Ethnicity •Ones that alter risk due to "missing" •Census/educational levels <p>PANCREAS</p> <ul style="list-style-type: none"> •2—Functional status •Primary insurance type •Ethnicity •Ones that alter risk due to "missing" •Ones that consistently fall out of models •Census/educational levels 	<p>KIDNEY</p> <ul style="list-style-type: none"> •3—Functional status •2—Insurance status •Ethnicity •Lumping infrequent data •Ones that consistently fall out of models •Census/educational levels •Cause of kidney failure <p>LIVER</p> <ul style="list-style-type: none"> •3—Functional status •Ethnicity •Primary insurance type •Ones that alter risk due to "missing" •Ones that consistently fall out of models •Census/educational levels •Donor citizenship, height, weight
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SRT leadership explained that when prioritizing additional data the following cost/benefit analysis is required:

- Each new data element carries a cost to the:
 - Transplant Center
 - Patient / 3rd Party Payer
 - OPTN / SRTR
- Potential Benefits
 - Model improvement (*i.e.* C-statistic) – no guarantees
 - Access to transplant for patients who may otherwise be excluded by risk-averse programs

Further, while prioritizing additional data, important considerations to keep in mind are:

- Reproducibility: Are there variations in methodology or interpretation that would reduce utility?
- Quality: Is the data element definition sufficiently clear to allow entry by the broad group of people currently entering OPTN data?
- Prevalence: Is the data element present in a high enough frequency to yield stable model coefficients?
- Timeline: A data element that is added to OPTN forms today will not be analyzable for future PSR models for at least 2-3 years

Regarding how to add more data elements, some of the lessons learned are that the OPTN Principles of Data Collection are not sufficient to govern additions/deletions from the OPTN dataset and that additional principles are needed to guide the process from a proposed data element to implementation into the OPTN dataset.

The Chair explained that this concluded the end of the background material for the DAC members. The Chair reminded the members of the February 2015 in-person meeting.

Upcoming Meetings

- December, 2014
- January, 2015
- February, 2015