Introduction
The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 8/11/2021 to discuss the following agenda items:

1. Establish Continuous Distribution of Lungs - Lung Committee
2. Data Collection to Evaluation Organ Logistics and Allocation - Operations & Safety Committee (OSC)
3. Report Primary Graft Dysfunction in Heart Transplant Recipients - Heart Committee
4. Office of Management and Budget (OMB) Update and Impacts
5. PHS Risk Criteria Data Collection - Ad Hoc Disease Transmission Advisory (DTAC)
6. Enhance Transplant Program Performance Monitoring System - Membership and Professional Standards Committee (MPSC)
7. Review Data Quality Report

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

1. Establish Continuous Distribution of Lungs - Lung Committee

UNOS staff provided an overview of the public comment proposal Establish Continuous Distribution of Lungs and requested feedback from the DAC.

Summary of discussion:

The purpose of this proposal is to better align lung allocation with community, ethical, and regulatory goals as well as medical advancements. All organs are intended to move to a continuous distribution allocation framework, which shifts how organs will be allocated from hard boundaries to considering individual candidates holistically through the use of composite allocation scores.

This proposal largely relies on existing data but intends to add data elements for extracorporeal membrane oxygenation (ECMO), type of assisted ventilation, and prior living donor status in WaitlistSM for lung candidates.

The Chair asked for more information on the post-implementation monitoring plan. UNOS staff commented that there is a robust monitoring for 6 months, 1 year, and 2 years following implementation. She noted that this new allocation framework allows for more flexibility for making adjustments as needs are identified.

UNOS staff asked the DAC members if they have feedback on how many decimal places should be calculated in the formula for the composite score. She commented that there needs be a balance between precision and meaningfulness. The Vice Chair commented that the number of decimal places
should depend on how many patients are at the top of the list in order to avoid ties. UNOS staff shared that the currently implemented Lung Allocation Score (LAS) has not needed to go beyond 4 decimal places. The members agreed that 4 to 5 decimal places should be sufficient.

A member commented that assisted ventilation categories should be updated to better reflect the current technology and devices being used. She commented that adding the ECMO data field will be helpful and asked if it will need to be updated on a regular basis. She raised a concern about patients being reported as being on ECMO even after they are weaned off support. UNOS staff commented that these variables will be updated at 6 months as is the current practice. The member commented that patients with a LAS over 50 with assisted ventilation require updates every 14 days. UNOS staff responded that the proposed system will replace LAS with the composite allocation score, so the timelines for more frequent updates will be more closely tied to specific assisted ventilation needs and will need to be updated every 28 days. UNOS staff also commented that the Lung Committee reworked the list of assisted ventilation options to better retain relevancy to avoid the need for frequent updates without being too vague to be unusable.

The Chair asked about how the Lung Committee approached considering program to program variability in how candidate sensitization is reported. UNOS staff commented that the Lung Committee discussed this and, specifically, calculated panel reactive antibody (CPRA). Trends identified in kidney candidates are being applied to lung candidates as a surrogate since CPRA is not consistently reported for lung candidates. By tying CPRA as a component of the composite score, it is intended to encourage members to submit this information about their candidates, if their candidate is more highly sensitized.

A member asked if submitting sensitization information will require listing the patient as being a required crossmatch. She expressed a concern for these candidates being bypassed in cases where there is no serum for crossmatching. The member recommended not requiring the reporting of sensitization information and encouraging organ procurement organizations (OPOs) to share serum for crossmatching in a process similar to what is currently done for kidneys. UNOS staff agreed to share these comments with the Lung Committee.

2. Data Collection to Evaluation Organ Logistics and Allocation - Operations & Safety Committee (OSC)

The OSC Immediate Past Chair provided an overview of the public comment proposal Data Collection to Evaluation Organ Logistics and Allocation and requested feedback from the DAC.

Summary of discussion:

The purpose of this proposal is to provide more insight into organ logistics and allocation with the goal to inform future policy development and to ensure data collection efforts are current and relevant. This proposal intends to add the following data elements:

- Organ check-out time (TransNet\textsuperscript{SM} or Deceased Donor Registration (DDR))
- Organ check-in time (Waitlist\textsuperscript{SM})
- Time of first anastomosis (Waitlist\textsuperscript{SM})

The proposal also intends to modify the existing data elements in the following ways to improve data quality:

- Type of Liver machine perfusion (DonorNet\textsuperscript{*})
  - Remove non-specified response field, “Other/Specify”
- Kidney(s) received on (Kidney – Transplant Recipient Registration (TRR))
  - Remove non-specified response field, “N/A”
• Kidney Pump Values: Time, Flow, Pressure, and Resistance (DonorNet™)
  o Collect initial, low/peak, and final values
• Left Lung/Right Lung machine perfusion intended or performed (DDR)*
  o Remove “intended or” from data field label
• Recovery Team # (DDR)*
  o Change from 6-digit provider number to 4-digit OPTN center code and 3-digit OPTN center type of the transplant center team recovering the organ

These modifications were addressed in the OPO Committee’s proposal Modify the Deceased Donor Registration (DDR) Form and are now Board approved. The OSC will include these modified data elements in their evaluation.

The proposal intends to modify the Organ Reason Codes on the DDR to remove “No recipient located (Code #208)” and “Positive human T-cell leukemia virus type 1 (HTLV-1) (Code #211)” and add a new code “No candidate on the match run.”

Capturing organ check-out time and organ check-in time is intended to document the chain of custody of the organ and act as a surrogate of organ transport time. The intention for capturing time of first anastomosis is to provide a more accurate timeline from recovery to transplant than what is currently being collected. When developing this proposal, the OSC considered the associated data burden, as well as future projects to collect data through GPS tracking and API.

The Chair commented that these proposed modifications seem very valuable, especially when validating and monitoring allocation changes post-implementation.

A member shared their support for collecting kidney pump values but questioned how to report when a kidney is pumped at one center, is then put back on ice, and then pumped again prior to transplant. The OSC representative commented that only the initial set of values will be collected when the kidney is first pumped since those values will be evaluated when deciding on an offer.

A member asked if there is a definition of check-out time for OPOs. The OSC representative responded that this will be when the organ is checked out on TransNetSM and is being packaged but commented more clarity could be provided.

A member asked if the definition of cold ischemic time (CIT) as it applies to organ perfusion will be clarified. The OSC representative commented that ischemic time will need to be considered going forward especially when also considering normothermic perfusion and instances in which an organ may have both warm and cold ischemic times.

A member asked if organ check-out time will be captured on the DDR or in TransNetSM, commenting that using TransNetSM would be cleaner and more accurate. UNOS staff shared that the preference is to capture this data in TransNetSM because the data will be more easily captured and accurate. This data element would be added to the DDR as a secondary option, if programming this data element in TransNetSM is not possible.

3. Report Primary Graft Dysfunction in Heart Transplant Recipients- Heart Committee

The Heart Transplantation Committee Vice Chair provided an overview of the public comment proposal Report Primary Graft Dysfunction in Heart Transplant Recipients and requested feedback from the DAC.
Summary of discussion:

This proposal intends to add the following data elements to the Heart Transplant Recipient Registration Form (TRR) to identify primary graft dysfunction (PGD) in recently transplanted heart recipients at 24 and 72 (+/- 4 hours) after the patient’s arrival to the intensive care unit (ICU).

- Primary Graft Dysfunction (yes or no)
- Left Ventricular Dysfunction (yes or no)
- Right Ventricular Dysfunction (yes or no)
- Left Ventricular Ejection Fraction (percentage)
- Right Atrial Pressure (mm Hg)
- Pulmonary Capillary Wedge Pressure (mm Hg)
- Pulmonary Artery Systolic Pressure/Pulmonary Artery Diastolic Pressure (mm Hg)
- Cardiac Output (liters/minute)
- Support Device (yes or no)
  - If Yes (right, left, or biventricular)
  - Type of Device (device name(s))
- Inotrope support (drug(s) and range dosages)
- Nitric Oxide following transplant (yes or no)
- Flolan following transplant (yes or no)

The Heart Vice Chair commented that these data elements and time points were determined by the Committee by referring to the International Society for Heart and Lung Transplantation (ISHLT) Consensus Statement for PGD as well as the feedback received from a preliminary round of public comment.

The proposal also intends to remove the data element “Airway Dehiscence” from the Heart TRR as it is not relevant for heart transplant recipients. This decision was supported during the request for feedback.

A member questioned if the grade of PGD (mild, moderate, severe) would be captured. The Heart Vice Chair commented that the program will determine if PGD is present (yes or no) and then the other data collected will be used to develop a national, objective definition using clinical values.

A member raised a concern about the significant burden associated with collecting and reporting the proposed data elements but acknowledged there needs to be a better understanding of PGD. The Heart Vice Chair commented that the 4-hour window at 24 and 72 hours was included in an attempt to lessen burden. The Heart Vice Chair also commented that the Heart Committee strived to propose as few additional data elements as feasible and solicited feedback from the community while developing the proposal.

A member commented that education will be needed to ensure those entering the data have access to the PGD diagnosis information from the physician either verbally or documented in the patient’s chart in order to be able to indicate “yes or no.” She commented that the dosing information is easy to find in the patient’s electronic medical records (EMR).

4. Office of Management and Budget (OMB) Update and Impacts

UNOS IT staff provided an overview and update on Office of Management and Budget (OMB) approval process.
Summary of discussion:
Starting in the early 1990’s, membership application forms and Transplant Information Electronic Data Interchange (TIEDI®) forms have been approved by the OMB. The purpose of these approvals is for the OMB to allow the public to evaluate burden impact of new or edited data collection. The current OPTN contract requires that all official OPTN data be collected on OMB approved instruments by the end of the contract period in 2023. Once the other UNet® applications beyond Membership forms and TIEDI® are approved by OMB over the next couple of years, all projects which propose substantive changes to data collection such as adding or removing data elements will need to go through the OMB approval process.

The OPTN has been working with HRSA to develop a process to incorporate other components of UNet® into the OMB process and modify OMB approved forms to incorporate changes approved by the OPTN Board. The definition of substantive change has expanded to include “…any revision to the collection of information that adds or deletes questions, changes the scope of inquiry or the population actually or potentially subject to inquiry, revises the method of collection or the procedure for sample selection, reinterprets compliance directives or other policy guidance, significantly changes the use of the information or otherwise meaningfully alters any aspect of the collection of information from that previously approved by OMB.”

Every OPTN Board of Directors (BOD) project that includes a substantive change to data collection or the addition of new data collection must go through the full OMB approval process prior to implementation. The OMB approval process will extend implementation timelines.

Beyond extending the implementation timeline, other impacts to this change may include the need to separate project releases based off system impact and OMB needs.

The Chair noted that in addition to the public comment cycle, the OMB process will add another year before the project is implemented. She commented that this is a long process for data related projects and asked how the DAC can help move projects forward. UNOS IT staff is working through ideas to figure out how to be most efficient for when projects are staged and go to the BOD for review and approval.

The Chair asked if removal of data elements need to follow the same OMB process. UNOS IT staff confirmed that OMB approval is still required for proposed removals.

5. PHS Risk Criteria Data Collection - Ad Hoc Disease Transmission Advisory (DTAC)

The DTAC Chair provided an overview of the public comment proposal PHS Risk Criteria Data Collection and requested feedback from the DAC.

Summary of discussion:
This proposal intends to collect more granular human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) risk criteria data to better evaluate trends with donor risk criteria that could impact patient safety and organ utilization. This data will be used to inform future iterations of the U.S. Public Health Service (PHS) Guideline and assess the impact of OPTN policy changes as well as support more efficient donor evaluation with discrete data fields.

The proposed data solution adds individual PHS Risk Criteria as discrete fields to the “overall risk” question in DonorNet® & TIEDI® Deceased Donor Registration (DDR) form. There will be options for “yes,” “no,” and “unknown” for all risk criteria as well as “not applicable” for two pediatric risk criteria.

A member questioned if the risk criteria would need to be entered in both DonorNet® and on the DDR. She raised a concern about potential discrepancies as well as increased burden associated with having
to enter the data twice. The DTAC Chair and UNOS staff confirmed that the information entered into DonorNet® would populate onto the DDR.

The Chair confirmed that multiple options can be selected. The DTAC Chair commented that for the first time, this more granular data collection will allow better understanding both the risk individually as well as the risk when multiple risk criteria are present.

A member asked if this expanded data collection will eliminate the need for OPOs to complete a PHS risk acknowledgement form. The DTAC Chair and UNOS staff confirmed that this proposal does not propose any modification to the existing risk acknowledgement process.

6. Enhance Transplant Program Performance Monitoring System - Membership and Professional Standards Committee (MPSC)

A member of MPSC provided an overview of the public comment proposal Enhance Transplant Program Performance Monitoring System and requested feedback from the DAC.

Summary of discussion:

With an intention to holistically evaluate transplant program performance, the MPSC is proposing the use of four separate metrics that each measure a distinct aspect of transplant program patient care. These metrics include waitlist mortality rate to measure waiting list patient care, offer acceptance rate to measure offer acceptance practices, 90-day post-transplant graft survival to measure perioperative care, and 1-year post-transplant graft survival conditional on 90-day graft survival to measure postoperative care. The MPSC member noted that these metrics do not relate to or have an effect of the Scientific Registry of Transplant Recipients (SRTR) public website. These new monitoring metrics are within the authority of the OPTN, can be influenced by transplant programs, will not require additional data collection, are risk-adjusted, and are intended to incentivize behaviors that will increase transplants.

The MPSC will monitor these metrics to intervene with programs to provide support if the metric is indicating there may be a patient safety issue. If the program is trending toward a threshold in which intervention may be necessary, the MPSC will provide a notice to the program to encourage self-evaluation and offer assistance.

The Chair acknowledged that although pre-waitlisting metrics are not currently collected by the OPTN, this metric should be considered if data is collected in the future. She also questioned if the MPSC discussed the inclusion of equity metrics and commented that the risk adjustments (e.g., adjusting for race or socioeconomic status) may make it more difficult for programs to identify ways to improve equity in access to transplantation. The MPSC member commented that part of the proposal’s plan is to incorporate aspirational or experimental monitoring metrics that would be tested and then potentially implemented once enough data is collected. He commented that the post-implementation monitoring plan is monitoring for Diversity, Equity, and Inclusion (DEI) issues to evaluate if the proposal, once implemented, disadvantages a group or exacerbates an existing disadvantage. He shared that the proposal intends to use the existing risk adjustment models used by SRTR. The Chair recommended delivering the metrics to transplant programs in a way that allows for a deeper dive or provides more context into differences such as stratifying by race or socioeconomic status.

The Chair commented that she supports the work the MPSC has done and supports moving away from the sole emphasis of performance being on post-transplant metrics.

A member asked if offers that are filtered by setting acceptance criteria (e.g., no donors over 50 years old) impact the organ offers acceptance rate metric. He commented that it is important to look at both
offers that are bypassed as well as those accepted. He also commented that this metric may put pressure on programs to accept organs that they are not necessarily comfortable accepting for their candidates. The MPSC member commented that the intent is to incentivize programs to only receive offers that they reasonably think they are going to accept because it makes the system more efficient. He continued that programs that are able to accept more challenging offers will get them sooner and may potentially have a higher likelihood of being able to use the organs because they will have less cold ischemic time. In addition, programs are only evaluated for offers they receive, not offers they have filtered out.

A member questioned how the waitlist mortality metric is impacted when programs have varied waitlist practices (e.g., one program does not list patients over 70 years old while another lists patients until age 80). The MPSC member responded that the waitlist mortality ratio is calculated by mortality that is observed compared to the mortality that is expected.

The Vice Chair asked if there are any mitigating efforts to limit programs from waiting to list a kidney patient until after they have accrued enough dialysis time to receive a transplant quickly and thereby potentially limiting the incidences of waitlist mortality. The Chair commented that programs may think they are able to influence their waitlist metrics by not listing patients who are at a low risk of transplant. The MPSC member responded that programs should list any patient they deem would benefit from transplant knowing that the metrics are risk adjusted. The Chair recommended providing adequate education for members.

7. Review Data Quality Report

UNOS Research staff provided an overview of the 2020 Data Quality Report and requested feedback about additional metrics to include in the 2021 report to improve usability of this tool to inform future recommendations from the DAC.

Summary of discussion:

The 2020 Data Quality Report, included in the meeting materials, focused on the four areas of timely data submission, changes to data after submission, potential discrepancies, and availability of known values (i.e. non-missing). The report also provided an overview of the impact of the COVID-19 pandemic on OPTN data submission. It was noted that the focus on changes to data after submission and availability of known values (i.e. non-missing) pertained primarily to the Modify Data Submission Policies (Data Lock) project and are recommended to be replaced with new metrics.

UNOS Research staff recommended keeping the timely data submission focus in the 2021 report. She also recommended keeping but expanding upon the potential data discrepancies to include more user data for the Centers for Medicare & Medicaid Services (CMS) Dialysis Data Report in UNOS Data Services portal as well as data on how often values are updated on Transplant Candidate Registration (TCR) /TRR after reviewing the Dialysis Data Report. Additionally, she recommended keeping the report section on COVID-19 data submission and amnesty policy impact.

The members were asked to provide recommendations on what information would be most valuable when assessing the quality of existing OPTN data. The Chair commented that it is important for the DAC to consider the data holistically and identify areas where they can make recommendations for improvement. She commented that the Committee needs to determine the best way to work with other committees and subject matter experts when looking at all data across all forms. She suggested first looking at where there is a significant amount of data missing in order to identify data elements for removal as well as focusing on areas where the data submitted is not accurate. She continued that the removal of data elements will reduce burden on OPTN members. UNOS Research staff agreed that the
data quality report could be a useful tool in identifying potential data elements for removal and any additional metrics added to the report could also be used as a starting point for working alongside of other committees when reviewing a form as a whole.

A member asked if the current quality report includes program and organ level detail on missing data or fields entered as “unknown.” UNOS Research staff commented that this level of detail is not currently included but could be easily added. The member commented that a program may have a 100% form completion rate but the majority of the data could have been entered as “unknown.” The member also supported a recommendation to review data relating to who is using the reports available in the Data Services Portal.

When considering the CMS Dialysis Data Report, a member suggested creating a linkage between End Stage Renal Disease Quality Reporting System (EQRS) and TIEDI® so the candidate dialysis data is populated into TIEDI® in order to improve consistency and accuracy.

The Chair asked the members to propose some general ideas for what metric could be regularly monitored to assess OPTN data quality. A member commented that she would be interested in how many programs are accessing the reports in the Data Services portal as there are many tools programs can use to monitor data quality. The Chair added that it could be useful to see if identified programs that may have more missing data improve their data quality over time. Another member commented that members may benefit from education around their ability to access data in EQRS.

The Chair asked for recommendations for how the DAC can partner with other committees that have subject matter expertise on specific data collection instruments to assist them in improving the data collected. A member suggested having optimization meetings with the other committees to provide them with recommendations for improvement. During this meeting, the DAC could present the amount of missing/unknown values on specific tools and use the data quality report as an optimization tool. UNOS Data Governance staff recommended collaborating more closely with the Policy Oversight Committee (POC) to encourage that reviewing existing data be prioritized as POC is tasked with approving resourcing.

Next steps:

UNOS Research staff will compile the ideas gathered during the discussion to create additional recommendations for the Committee to review prior to the finalization of the 2021 Data Quality Report.

Upcoming Meetings

- September 13, 2021
- October 11, 2021
Attendance

- **Committee Members**
  - Alicia Redden
  - Anna Mello
  - Benjamin Schleich
  - Bilal Mahmood
  - Colleen O'Donnell Flores
  - Daniel Stanton
  - Heather Hickland
  - Jamie Bucio
  - Krishnaraj Mahendraraj
  - Kristine Browning
  - Lauren Kearns
  - Macey Levan
  - Melissa McQueen
  - Rachel Patzer
  - Sumit Mohan

- **HRSA Representatives**
  - Adriana Martinez
  - Shannon Dunne

- **SRTR Staff**
  - Bert Kasiske
  - Jon Snyder
  - Maryam Valapour

- **UNOS Staff**
  - Abby Fox
  - Ann-Marie Leary
  - Betsy Warnick
  - Elizabeth Miller
  - Eric Messick
  - James Alcorn
  - Joann White
  - Kiana Stewart
  - Kimberly Uccellini
  - Krissy Laurie
  - Kristine Althaus
  - Lauren Mauk
  - Leah Slife
  - Meghan McDermott
  - Nicole Benjamin
  - Sally Aungier
  - Samantha Noreen
  - Sarah Konigsburg
  - Susan Tlusty

- **Other Attendees**
  - Dominic Adorno
  - Ricardo La Hoz
- Richard Formica
- Rocky Daly