At-a-Glance

- **Proposed Modifications to Data Elements on the following Tiedi® forms[1]: Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-up (TRF), Living Donor Registration (LDR), Living Donor Follow-up (LDF), Deceased Donor Registration (DDR), Histocompatibility Form (HF), and approval of a new Explant Pathology Form for Liver Recipients**.

- **Affected Policy:** N/A

- **Policy Oversight Committee**

- All OPTN forms must be reviewed and approved by the Office of Management and Budget (OMB) every three years. The OPTN initiated a review of the data elements in order to identify any necessary changes. . This proposal will outline the recommended modifications to the data elements in Tiedi®. These recommendations follow a comprehensive review of all the data elements by OPTN Committees, the Ad Hoc Data Management Group, an Expert Panel on Cardiovascular Risk Factors in Renal Candidates/Recipients, and the Policy Oversight Committee. The purpose of the changes is to add important variables that are not currently collected, clarify or modify questions on the forms, and eliminate variables that are redundant or no longer needed.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

[1] **Tiedi**® Through the Transplant Information Electronic Data Interchange (Tiedi®) section of UNet℠, data coordinators and program staff members receive, complete, and submit data on transplant candidates, recipients, and donors to OPTN/UNOS.

Proposed Modifications to Data Elements on the following Tiedi® forms: Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-up (TRF), Living Donor Registration (LDR), Living Donor Follow-up (LDF), Deceased Donor Registration (DDR), Histocompatibility Form (HF), and approval of a new Explant Pathology Form for Liver Recipients.

Affected Policy: N/A

Policy Oversight Committee

Summary and Goals of the Proposal:

All OPTN forms must be reviewed and approved by the Office of Management and Budget (OMB) every three years. The OPTN initiated a review of the data elements in order to identify any necessary changes to the forms. This proposal will outline the recommended modifications to the data elements in Tiedi®. These recommendations follow a comprehensive review of all the data elements by OPTN Committees, the Ad Hoc Data Management Group (AHDMG), an Expert Panel on Cardiovascular Risk Factors in Renal Candidates/Recipients (Expert Panel), and the Policy Oversight Committee (POC). The purpose of the changes is to add important variables that are not currently collected, clarify or modify questions on the forms, and eliminate variables that are redundant or no longer needed.

Background and Significance of the Proposal:

The National Organ Transplant Act of 1984 requires that the OPTN "collect, analyze, and publish data concerning organ donation and transplants." OPTN members are required to complete and submit a series of data collection forms. Currently, forms are submitted via UNet^{SM}, a secure web-based data collection system. The OPTN has made major modifications to the data collection instruments in 1994, 1999, and 2004, as well as periodic minor modifications. In 2006, the OPTN undertook a comprehensive "data reduction" project following a strategic planning meeting. The purpose of that project was to develop an efficient data collection system and to ensure that each data element met at least one of the goals of the OPTN Principles of Data Collection[2] that were approved by the OPTN/UNOS Board of Directors. The Board of Directors also required that all new data elements added to OPTN data collection systems meet these principles. The primary goal of the principles is to improve patient outcomes.

In early 2009, the OPTN initiated the review of all Tiedi® forms that require OMB approval. Due to the increasing importance placed on transplant center performance (e.g., program-specific reports) by both the OPTN and the Centers for Medicare and Medicaid Services, the OPTN requested input from experts in the transplant community. OPTN Committees were given an opportunity to provide input relating to their specific areas of expertise and forward their recommendations to the Ad Hoc Data Management Group (AHDMG). The AHDMG, which was formed in 2006 and charged with making data-related recommendations to the POC, led the review of recommendations being submitted by the various groups. This working group is comprised of experts in the field of transplantation and includes representation from various specialties, including data collection methods and organ-specific expertise.

OPTN Committee Deliberations

[2] 1. Develop transplant, donation, and allocation policies. 2. OPTN member compliance with policies. 3. Determine member-specific performance. 4. Ensure patient safety. 5. Fulfill the requirements under the Final Rule.

OPTN Committees were given an opportunity to provide input relating to their specific areas of expertise and each Tiedi form was reviewed by at least one Committee. The members reviewed existing data elements and proposed additions that were in accordance with the OPTN Principles of Data Collection. Much of the deliberations focused on adding elements to data collection forms that would potentially be important for improving the predictive power of models used to assess transplant program performance or for patient safety.

Ad Hoc Data Management Group Review Process

The AHDMG received a comprehensive list of proposed changes to the data elements provided by OPTN committees. This list included the proposed change, description of the data element, the applicable principle of data collection, and rationale for the change. AHDMG members were asked to review a spreadsheet containing the proposed changes and provide any comments and vote on each item. Those items that did not receive a unanimous approval vote were discussed during conference calls on October 29, 2009; November 10, 2009; and November 16, 2009. A subsequent conference call was held on January 22, 2010 to discuss recommendations from the Expert Panel, the OPTN/UNOS Kidney Transplantation Committee, and the SRTR. A summary of the approved recommendations from all of these calls can be found in **Appendix A.** The summary document lists all the recommended additions, modifications, and deletions by form. For further details, please refer to to **Exhibit A** at http://optn.transplant.hrsa.gov/ContentDocuments/OMB_PublicComment.xls

In addition to the changes to the OPTN data collection forms, the AHDMG also reviewed and approved a new Explant Pathology Form for Liver Recipients. This form was developed by the Pathology Working Group in preparation for the November 17-18, 2008 Hepatocellular Carcinoma (HCC) Consensus Conference held in Chicago, Illinois. Following the conference, the Liver and Intestinal Organ Transplantation Committee reviewed the proposed form and suggested that it be collected on all candidates with HCC regardless of whether they receive additional MELD exception points for HCC. This form is also included in **Appendix A**.

Expert Panel on Cardiovascular Risks Factors in Renal Candidates/Recipients

A recent criticism of the OPTN data collection forms has been the lack of elements regarding a patient's cardiovascular history, particularly for kidney. Recognizing the complexity of this issue and the many possible measures that could be considered, the OPTN formed a panel, made up of experts in the field of nephrology and cardiology, to develop recommendations for cardiovascular-related data elements to be collected on kidney transplant candidates and recipients. The purpose was to develop evidence-based recommendations for the addition of these elements to the OPTN data collection system in order to provide the OPTN and the SRTR with the necessary data to address the needs of the transplant community and other federal agencies that monitor clinical performance. The panelists met by conference call on November 23, 2009 and completed their discussions using an electronic survey. These final recommendations were forwarded to the AHDMG and were discussed during a January 22, 2010 conference call. The POC reviewed the recommendations from the Expert Panel and AHDMG during a conference call on January 28, 2010. The POC approved the recommendations to collect the following cardiovascular data elements: Committee vote: 7 in favor, 0 opposed, and 0 abstentions.

- Ejection Fraction
- Cardiac Interventions
- Cardiac Troponin T
- Peripheral Vascular Disease
- Tobacco Use
- Atrial Fibrillation

Further details about the Expert Panel and their recommendations can be found in **Appendix B**.

Policy Oversight Review

The Policy Oversight Committee reviewed and discussed the recommendations from the AHDMG during conference calls on January 8, 2010 and January 28, 2010. For a summary of changes as well as comments and votes from the POC, please refer to **Appendix A**.

Summary of Changes to Data Elements

- Overall - 197 data elements were added, 131 were deleted, and 31 were modified
- TCR: 55 additions, 5 deletions, 4 modifications
- TRR: 50 additions, 6 deletions, 3 modifications
- TRF: 18 additions, 4 deletions, 3 modifications
- LDR: 6 additions, 16 deletions, 11 modifications
- LDF: 20 additions, 3 deletions
- DDR: 42 additions, 11 deletions, 10 modifications
- HF: 6 additions, 86 deletions

Expected Implementation Plan:

This proposal will require programming in UNet[sm] in order to make necessary changes to the online forms.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audiences**	**Deliver Method**	**Timeframe**
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Transplant Coordinators, Transplant Surgeons, Transplant Physicians, Transplant Center Program Directors, Transplant Administrators, OPO Staff	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday of each month	30 days after the board approves the changes.
System Notice	UNet[SM] users	Through UNet[SM]	4 weeks before implementation, upon implementation

OMB Summary for POC Review

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Important Information

Please note that the Policy Oversight Committee reviewed the recommendations from the Ad Hoc Data Management Group during conference calls held on January 8, 2010, and January 28, 2010. All data elements marked with an asterisk (*) were reviewed and voted on during the January 28, 2010, meeting. The remainder of the data elements were reviewed and voted on during the initial conference call on the January 8, 2010.

TRANSPLANT CANDIDATE REGISTRATION (TCR) FORM

Data elements proposed on TCR for <u>all organ types</u>:

- *Add*:
    - *Country of Permanent Residence
    - *Diabetes - age at first medical treatment (oral glycemic agents or insulin) – already collected for Kidney TCR as age of diabetes onset (reworded on KI TCR)
    - *Drug-treated systemic hypertension
    - *Diagnosis of CVA or TIA or surgical/percutaneous revascularization for cerebrovascular disease (Yes, No)
        - *If yes, interventions for cerebrovascular disease
    - *HIV Status
    - *HBV Surface Antigen
    - *HCV
    - *Coronary bypass
    - *Coronary angioplasty and/or stent
    - *Myocardial infarction
    - *Other cardiac disease
    - *History of cigarette use (Yes, No); (already collected for Thoracic)
        - If Yes, check # of pack years (0-10, 11-20, 21-30, 31-40, 41-50, >50, unknown pack years);
        - If Yes, enter duration of abstinence (in months): 0-2, 3-12, 13-24, 25-36, 37-48, 49-60, >60, continues to smoke, unknown duration
    - *Other tobacco use (Yes, No, Unknown) (already collected for Thoracic)
    - *Cirrhosis (already collected for Liver)

- *Delete*:
    - Academic progress (candidates aged 18-19 only)
    - Academic activity level (candidates aged 18-19 only)
    - *Previous PA Islet Infusion (pediatric forms only)

- *Modify*:
    - *Diabetes (No, Type I, Type II) – remove unknown
    - *Any previous malignancy (Yes, No) – remove unknown
    - *Race to follow CMS 2728 form (White, Black or African American, American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander)
    - *Ethnicity (Not Hispanic or Latino, Hispanic or Latino)

- **POC Review**

  The POC had a lengthy discussion regarding the items that were recommended for deletion from the TCR by the Transplant Administrators Committee. During its deliberations, the AHDMG voted to keep these items. The main concern was the ability of transplant centers to collect accurate information because of the lack of consistent definitions for some of the data elements. An example of this is the Karnofsky/Lansky tool, which is a valid and reliable instrument when utilized appropriately. There was a concern raised, however, that there is inconsistency across the country in how transplant programs incorporate this tool into their physical assessments. The POC agreed with these concerns, but thought that the information should still be collected and remain on the forms. The POC also decided that working for income, cognitive development, motor development, academic progress, and academic activity level questions should remain on the forms. There was a recommendation to form a joint working group to further address these concerns, possibly through enhanced documentation or educational efforts. The POC declined to add cancer-free interval to the form. The POC voted to approve the AHDMG's recommendations by a vote of 7 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, including the decision not to add items on history of alcoholism or history of drug abuse by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Kidney TCR</u>:

- *Add*:
  - *Secondary Diagnosis
  - *Tertiary Diagnosis
  - *C-peptide value if Type I Diabetes
  - *Is candidate on insulin or oral glycemic agents (if Type I or Type diabetes)? (Yes, No)
  - *Dialysis (Hemodialysis, Peritoneal Dialysis, No Dialysis)
  - *Age of Onset of Drug Treated Systemic Hypertension
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
  - *Ejection Fraction value - allow option for Not done
  - *Method for Ejection Fraction: Echo, Cath, Nuclear Scan
  - *Diagnosis of Sleep Apnea (Yes/No)

        - If Yes, Treated with CPAP or surgery (Yes/No)
    - *Cardiac Troponin T (enter actual value) - allow option for Not done
    - *Atrial fibrillation (Yes/No)

- *Delete*:
    - *Drug Treated COPD

- **POC Review**

  *The POC voted to approve the AHDMG's recommendations with one modification to the question regarding sleep apnea, changing it from a single yes or no question about treatment for sleep apnea to two questions: diagnosis (yes/no) and treatment (yes/no): POC vote was 7 in favor, 0 opposed, and 0 abstentions.

  *The POC discussed the recommendations of the Expert Panel and voted to add atrial fibrillation to the forms by a vote of 7-0-0. All other approved Expert Panel recommendations were covered by committee recommendations.

Data elements proposed on <u>Kidney-Pancreas TCR</u>:

- *Add*:
    - Is candidate on insulin or oral glycemic agents? (yes/no)
        - If yes, average daily insulin units
        - If yes, C-Peptide
            - If yes, C-Peptide method
    - HbA1c
    - *Is the candidate listed for a pancreas as part of a multi-visceral transplant?
    - *Documented coronary artery disease interventions
    - *Secondary Diagnosis
    - *Tertiary Diagnosis
    - *C-peptide value if Type I Diabetes
    - *Dialysis (Hemodialysis, Peritoneal Dialysis, No Dialysis)
    - *Age of Onset of Drug Treated Systemic Hypertension
    - *Peripheral vascular disease requiring intervention (Yes, No)

        - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
    - *Ejection Fraction value - allow option for Not done
    - *Method for Ejection Fraction: Echo, Cath, Nuclear Scan
    - * Diagnosis of Sleep Apnea (Yes/No)
        - If Yes, Treated with CPAP or surgery (Yes/No)
    - *Cardiac Troponin T (enter actual value) - allow option for Not done
    - *Atrial fibrillation (Yes/No)

- *Delete*:
    - *Drug Treated COPD

- **POC Review**

  No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, with one modification to the question regarding sleep apnea: POC vote was 7 in favor, 0 opposed, and 0 abstentions.

  *The POC discussed the recommendations of the Expert Panel and voted to add atrial fibrillation to the forms by a vote of 7-0-0. All other approved Expert Panel recommendations were covered by committee recommendations.

Data elements proposed on <u>Pancreas TCR</u>:

- *Add*:
    - Is candidate on insulin or oral glycemic agents? (yes/no)
        - If yes, average daily insulin units
        - If yes, C-Peptide
            - If yes, C-Peptide method
    - HbA1c
    - *Is the candidate listed for a pancreas as part of a multi-visceral transplant?
    - *Documented coronary artery disease interventions
    - *Age of Onset of Drug Treated Systemic Hypertension
    - *Peripheral vascular disease requiring intervention (Yes, No)

        - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
    - *Ejection Fraction value - allow option for Not done
    - *Method for Ejection Fraction: Echo, Cath, Nuclear Scan
    - * Diagnosis of Sleep Apnea (Yes/No)
        - If Yes, Treated with CPAP or surgery (Yes/No)
    - *Cardiac Troponin T (enter actual value) - allow option for Not done.

- **POC Review**

  No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations with one modification to the question regarding sleep apnea. The POC also voted not to add GFR to the form: POC vote: 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Liver TCR</u>:

- *Add*
    - Has the candidate ever had a diagnosis of HCC?
    - Hepatopulmonary syndrome that meets exception criteria?
    - Portopulmonary syndrome that meets exception criteria?

- **POC Review**

  No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendation not to add GFR to the form by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Intestine TCR</u>:

- *Add*
    - Total bilirubin (adult candidates)

- **POC Review**

  No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, including the AHDMG's decision not to add GFR to the form, by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Heart TCR</u>:

- *Add*:
  - *Medical Condition at Time of Listing (for pediatric candidates)
  - *LVAD implant date
  - *RVAD implant date
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
  - *Right arterial pressure/central venous pressure (CVP)
  - *Defibrillator with biventricular pacemaker
  - *Biventricular pacemaker
  - *Serum bilirubin
  - *BNP
  - *Pro-BNP
  - *Systolic blood pressure
  - *Serum sodium
  - *Serum hemoglobin
  - *NYHA Class

- *Delete*:
  - Previous pancreas islet infusion

- **POC Review**

  No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

  *The POC had considerable discussions about the AHDMG's recommendation not to add VAD implant date to the heart TCR forms. The Thoracic Committee had noted that this duplicates

information that has been approved by the Board of Directors for collection at the time of waiting list removal. However, the SRTR noted that because the VADs have become substantially more durable, patients can sometimes live with these implanted devices for years and may remain on the waiting list. Because information regarding VAD usage is critical for developing a Heart Allocation Score, the SRTR thought that collection of this additional element was warranted. The POC voted to add this information to the heart TCR form: 4 in favor, 3 opposed, and 0 abstentions.

*The POC voted to modify some of the changes requested by the SRTR to agree with the recommendations of the Thoracic Committee. They voted not to add BUN, systolic blood pressure, heart rate, total cholesterol, serum uric acid, lymphocyte count, and medications.

*The POC also voted not to add GFR to the form as the components necessary for calculation of the estimated GFR are already collected.

Data elements proposed on <u>Lung TCR</u>:

- *Add*:
  - *BNP
  - *Pro-BNP
  - *Serum bilirubin
  - *Defibrillator
  - *Defibrillator with biventricular pacemaker
  - *Biventricular pacemaker
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply

- *Delete*:
  - Previous pancreas islet infusion

- **POC Review**

No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

*The POC voted to modify some of the changes requested by the SRTR to agree with the recommendations of the Thoracic Committee. They voted not to add most recent RA (CVP) to

the form because it is already collected on the waiting list. They voted to add a defibrillator item, as well as a child question for biventricular pacemaker. Also in agreement with Thoracic Committee recommendations, the POC voted not to add BUN or medications. The POC supported the AHDMG's decision not to add GFR to the form. The POC's vote to modify these AHDMG recommendations was 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Heart-Lung TCR</u>:

- *Add*:
  - *Medical Condition at Time of Listing (for pediatric candidates)
  - *LVAD implant date
  - *RVAD implant date
  - *Defibrillator with biventricular pacemaker
  - *Biventricular pacemaker
  - *Serum bilirubin
  - *BNP
  - *Pro-BNP
  - *Systolic blood pressure
  - *Serum sodium
  - *Serum hemoglobin
  - *NYHA Class
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply

- *Delete*:
  - Previous pancreas islet infusion

- **POC Review**

  No discussion: Approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

  * The POC voted to modify some of the changes requested by the SRTR to agree with the recommendations of the Thoracic Committee. They voted not to add most recent RA (CVP) to

the form because it is already collected on the waiting list. Also in agreement with Thoracic Committee recommendations, the POC voted not to add BUN, diastolic blood pressure, heart rate, total cholesterol, serum uric acid, lymphocyte count, or medications. They also voted not to add GFR to the form. The vote was 7 in favor, 0 opposed, and 0 abstentions.

TRANSPLANT RECIPIENT REGISTRATION (TRR) FORM

Data elements proposed on TRR for <u>all organ types</u>:

- *Add to existing forms*:
    - CMV total (replacement for CMV IgM)
    - *HBV Surface Antibody Total
    - *Secondary/First Assistant Surgeon
    - *Diabetes (Type I, Type II, No)
    - *Diabetes age at first medical treatment (oral glycemic agents or insulin)
    - *Drug-treated systemic hypertension
    - *Diagnosis of CVA or TIA or surgical/percutaneous revascularization for cerebrovascular disease (Yes, No)
        - *If yes, interventions for cerebrovascular disease
    - *Myocardial infarction
    - *Coronary bypass
    - *Coronary angioplasty and/or stent
    - *Other cardiac disease
    - *History of cigarette use (Yes, No);
        - If Yes, check # of pack years (0-10, 11-20, 21-30, 31-40, 41-50, >50, unknown pack years);
        - If Yes, enter duration of abstinence (in months): 0-2, 3-12, 13-24, 25-36, 37-48, 49-60, >60, continues to smoke, unknown duration
    - * Other tobacco use (Yes, No, Unknown)
    - *Was the patient actively desensitized? (Yes, No)
    - *Islet cell recipient
    - *Cirrhosis (already collected for liver)

- *Delete*:
    - Academic progress (recipients aged 18-19 only)
    - Academic activity level (recipients aged 18-19 only)
    - Malignancies between listing and transplant
    - CMV IgM (replaced by CMV total)

- **POC Review**

  As with the TCR, the Transplant Administrators Committee expressed concerns about the items it recommended for deletion. Their concerns were noted and will be addressed by the working group mentioned above in the TCR section. The POC decided that working for income and functional status items should remain on the forms. Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, including declining to add history of alcoholism and history of drug abuse to the form, by a vote of 7 in favor, 0 opposed, and 0 abstentions.

  *Note that the decision to delete malignancies between listing and transplant conflicts with the decision to support the Kidney Committee's recommendation to keep the item and delete 'unknown' as an option.

Data elements proposed on <u>Kidney TRR</u>:

- *Add*
  - *Secondary Diagnosis
  - *Tertiary Diagnosis
  - *Age of Onset of Drug Treated Systemic Hypertension
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
  - *Ejection Fraction value - allow option for Not done
  - *Method for Ejection Fraction: Echo, Cath, Nuclear Scan
  - *Diagnosis of Sleep Apnea (Yes/No)
    - *If Yes, Treated by CPAP or surgery (Yes/No)
  - *Cardiac Troponin T (enter actual value) - allow option for Not done
  - *Incidental tumor at transplant – select type of tumor for each of the following and specify if benign or malignant:
    - in donor graft
    - in recipient native kidney
    - in prior transplanted graft
  - *Atrial fibrillation (Yes/No)

- *Delete*:
    - *Pre-transplant transfusions

- *Modify*:
    - *Previous pregnancies (Yes, No) - currently collect the number of pregnancies if Yes to previous pregnancies
    - *Malignancies between listing and transplant (Yes, No) – remove unknown

- **POC Review**

*The POC voted to approve the AHDMG's recommendations with only one suggested modification to the question regarding sleep apnea, as noted above. POC vote: 7 in favor, 0 opposed, and 0 abstentions.

*Note that the decision to support the Kidney Committee's recommendation to keep the item about malignancies between listing and transplant and delete 'unknown' as an option conflicts with the decision to delete the item on the TRR for all organs.

*The POC discussed the recommendations of the Expert Panel and voted to add atrial fibrillation to the forms by a vote of 7-0-0. All other approved Expert Panel recommendations were covered by committee recommendations.

Data elements proposed on <u>Kidney-Pancreas TRR</u>:

- *Add:*
    - Is candidate on insulin or oral glycemic agents? (yes/no)
        - If yes, average daily insulin units
    - *Did the recipient receive a pancreas as part of a multi-visceral transplant?
    - *Documented coronary artery disease interventions
    - *Secondary Diagnosis
    - *Tertiary Diagnosis
    - *Age of Onset of Drug Treated Systemic Hypertension
    - *Peripheral vascular disease requiring intervention (Yes, No)
        - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
    - *Ejection Fraction value - allow option for Not done

- *Method for Ejection Fraction: Echo, Cath, Nuclear Scan
- * Diagnosis of Sleep Apnea (Yes/No)
    - If Yes, Treated by CPAP or surgery (Yes/No)
- *Cardiac Troponin T (enter actual value) - allow option for Not done
- *Incidental tumor at transplant – select type of tumor for each of the following and specify if benign or malignant:
    --in donor graft
    --in recipient native kidney
    --in prior transplanted graft
- *Atrial fibrillation (Yes/No)

- *Delete*:
    - Medical condition at time of transplant
    - *Pre-transplant transfusions

- *Modify*:
    - *Previous pregnancies (Yes, No) - currently collect the number of pregnancies if Yes to previous pregnancies
    - *Malignancies between listing and transplant (Yes, No) – remove unknown

- **POC Review**

No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

*The POC voted to approve the AHDMG's recommendations with only one suggested modification to the question regarding sleep apnea as noted above. POC vote: 7 in favor, 0 opposed, and 0 abstentions.

*Note that the decision to support the Kidney Committee's recommendation to keep the item about malignancies between listing and transplant and delete 'unknown' as an option conflicts with the decision to delete the item on the TCR for all organs.

*The POC discussed the recommendations of the Expert Panel and voted to add atrial fibrillation to the forms by a vote of 7-0-0. All other approved Expert Panel recommendations were covered by committee recommendations.

Data elements proposed on <u>Pancreas TRR</u>:

- *Add*:
    - Is candidate on insulin or oral glycemic agents?
        - If yes, average daily insulin units
    - *Did the recipient receive a pancreas as part of a multi-visceral transplant?
    - *Documented coronary artery disease interventions
    - *Age of Onset of Drug Treated Systemic Hypertension
    - *Peripheral vascular disease requiring intervention (Yes, No)
        - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply
    - *Ejection Fraction value - allow option for Not done
    - *Method for Ejection Fraction: Echo, Cath, Nuclear Scan
    - *Diagnosis of Sleep Apnea (Yes/No)
        - If Yes, Treated by CPAP or surgery (Yes/No)
    - *Cardiac Troponin T (enter actual value) - allow option for Not done

- *Delete*:
    - Medical condition at time of transplant

- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, including the AHDMG's decision not to add GFR to the form, with only one suggested modification to the question regarding sleep apnea, as noted above. POC vote: 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Liver TRR</u>:

- *Add*
    - Has the recipient ever had a diagnosis of HCC?
    - Post-Transplant Biliary Complications?

- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, including the AHDMG's decision not to add GFR, recipient sodium, or reoccurrence of HCC to the form, by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Intestine TRR</u>:

No changes proposed for intestine only.

Data elements proposed on <u>Heart TRR</u>:

- *Add*:
  - Ex vivo perfusion
  - Tricuspid valve annuloplasty
  - Any prior thoracic surgery (add for adults, modify for pediatrics)
  - Any prior sternotomies
  - Any prior left thoracotomies; any prior right thoracotomies
  - *Right arterial pressure/central venous pressure (CVP)
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply

- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve some of the AHDMG's recommendations, including the AHDMG's decision not to add GFR or recipient sodium to the form, by a vote of 7 in favor, 0 opposed, and 0 abstentions. The POC also voted to modify some of the changes requested by the SRTR

to agree with the recommendations of the Thoracic Committee. They voted not to add BUN or medications.

Data elements proposed on <u>Lung TRR</u>:

- *Add*:
  - Ex vivo perfusion
  - Any prior thoracic surgery (add for adults, modify for pediatrics)
  - Any prior sternotomies
  - Any prior left thoracotomies
  - Any prior right thoractomies
  - Intubated at 24 hours and at 72 hours
  - PaO_2 at 24 hours and at 72 hours
  - FiO_2 at 24 hours and at 72 hours
  - ECMO at 24 hours and at 72 hours
  - Inhaled NO at 24 hours and at 72 hours
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply

- **POC Review**

No discussion: Approved AHDMG recommendations, including the AHDMG's decision not to add PGD Grade 1-3 to the form: 8 in favor, 0 opposed, and 0 abstentions

*The POC voted to approve the AHDMG's recommendations, including the AHDMG's decision not to add GFR or recipient sodium, by a vote of 7 in favor, 0 opposed, and 0 abstentions.

*The POC also voted to modify some of the changes requested by the SRTR to agree with the recommendations of the Thoracic Committee. They voted not to add most recent RA (CVP) to the form because it is already collected on the waiting list. They also voted not to add BUN or medications.

Data elements proposed on <u>Heart-Lung TRR</u>:

- *Add*:
  - Ex vivo perfusion
  - Tricuspid valve annuloplasty
  - Any prior thoracic surgery (add for adults, modify for pediatrics)
  - Any prior sternotomies
  - Any prior left thoracotomies; any prior right thoracotomies
  - Intubated at 24 hours and at 72 hours
  - PaO_2 at 24 hours and at 72 hours
  - FiO_2 at 24 hours and at 72 hours
  - ECMO at 24 hours and at 72 hours
  - Inhaled NO at 24 hours and at 72 hours
  - *Peripheral vascular disease requiring intervention (Yes, No)
    - *Intervention type if yes to peripheral vascular disease requiring intervention: "surgical bypass, percutaneous angioplasty or stent, amputation (other than toe)" - check all that apply

- **POC Review**

  No discussion: Approved AHDMG recommendations, including the AHDMG's decision not to add PGD Grade 1-3 to the form: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's recommendations, including the AHDMG's decision not to add GFR or recipient sodium to the form, by a vote of 7 in favor, 0 opposed, and 0 abstentions.

  *The POC also voted to modify some of the changes requested by the SRTR to agree with the recommendations of the Thoracic Committee. They voted not to add most recent RA (CVP) to the form because it is already collected on the waiting list. They also voted not to add BUN or medications.

TRANSPLANT RECIPIENT FOLLOWUP (TRF) FORM

Data elements proposed on TRF for up to 5 years for <u>all organ types</u>:

- *Add*:
    - HIV serology results (if done, otherwise answer "not done")
    - HIV NAT results (if done, otherwise answer "not done")
    - HbsAg results (if done, otherwise answer "not done")
    - HBV DNA results (if done, otherwise answer "not done")
    - HBV Core antibody results (if done, otherwise answer "not done")
    - HCV serology results (if done, otherwise answer "not done")
    - HCV NAT results (if done, otherwise answer "not done")
    - Malignancy Type (Drop-downs and specify text for all but three skin sites and Kaposi's sarcomas) – collected after 5 years for liver
    - Malignancy Site for De Novo, Recurrent, and Donor Related Tumors – collected after 5 years for liver
    - EBV status of Tumor for PTLD/Lymphoma

- *Delete*:
    - Academic progress (recipients aged 18-19 only)
    - Academic activity level (recipients aged 18-19 only)
    - Physician name

- **POC Review**

  There was concern from the POC about keeping the "physician name" on the forms because there is no clear definition about which physician should be listed, which could lead to collection of inconsistent data. As a result, the POC voted to delete this field as requested. The POC also decided that working for income, cognitive development, motor development, and functional status should remain on the forms. The POC's vote was 7 in favor, 0 opposed, and 0 abstentions.

  *The POC voted 7 in favor, 0 opposed, and 0 abstentions not to add date of acute rejection episode to the forms.

Data elements proposed on <u>Kidney TRF</u>:

- *Atrial fibrillation (Yes/No)

*The POC discussed the recommendations of the Expert Panel and voted to add atrial fibrillation to the forms by a vote of 7-0-0. All other approved Expert Panel recommendations were covered by committee recommendations.

Data elements proposed on <u>Kidney-Pancreas TRF</u>:

- *Add*:
  - Is candidate on insulin or oral glycemic agents? (yes/no)
    - If yes, average daily insulin units
    - If yes, C-Peptide
      - If yes, C-Peptide method
  - HbA1c
  - *Atrial fibrillation (Yes/No)

- **POC Review**

No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions

*The POC discussed the recommendations of the Expert Panel and voted to add atrial fibrillation to the forms by a vote of 7-0-0. All other approved Expert Panel recommendations were covered by committee recommendations.

Data elements proposed on <u>Pancreas TRF</u>:

- *Add*:
  - Is candidate on insulin or oral glycemic agents? (yes/no)
    - If yes, average daily insulin units
    - If yes, C-Peptide
      - If yes, C-Peptide method
  - HbA1c

- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions

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Data elements proposed on <u>Liver TRF</u>:

- *Add*
  - Biliary Complications

- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC voted to approve the AHDMG's decision not to add recurrence of HCC to the form by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Intestine TRF</u>:

- *Add*:
  - Total bilirubin (adult recipients)
  - Most recent lab date (adult recipients)

- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions

---

Data elements proposed on <u>Heart TRF</u>:

- *Modify*:
  - Creatinine (actual rather than >2.5 mg/dl) for all recipients
  - Dialysis for all recipients
  - Renal transplant for all recipients

- *Delete*:
    - Renal dysfunction
- **POC Review**

  No discussion: Approved AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions

---

Data elements proposed on <u>Lung TRF</u>:

- *Modify*:
    - Creatinine (actual rather than >2.5 mg/dl) for all recipients
    - Dialysis for all recipients
    - Renal transplant for all recipients

- *Delete*:
    - Renal dysfunction

- **POC Review**

  No discussion: Approved AHDMG recommendations, including their decision not to add to the form an item about balloon bronchoplasty if bronchial stricture: 8 in favor, 0 opposed, and 0 abstentions

---

Data elements proposed on <u>Heart-Lung TRF</u>:

- *Modify*:
    - Creatinine (actual rather than >2.5 mg/dl) for all recipients
    - Dialysis for all recipients
    - Renal transplant for all recipient

- *Delete*:
    - Renal dysfunction

- **POC Review**

No discussion: Approved AHDMG recommendations, including their decision not to add to the form an item about balloon bronchoplasty if bronchial stricture: 8 in favor, 0 opposed, and 0 abstentions

LIVING DONOR REGISTRATION (LDR) FORM

- *Add*
    - Type of health insurance
    - Conversion from Laparoscopic to Open (for liver donors, already collected for KI donors)
    - EBV Total
    - *HIV status
    - *Country of Permanent Residence
    - *History of Birth Control Pill use

- *Modify*
    - Change health insurance question to specify at donation
    - Change label from HBV DNA to HBV DNA (NAT/PCR) , CMV to CMV Total, and from HCV RNA to HCV RNA (NAT/PCR)
    - Make mandatory:
        - State of residence
        - Donor recovery facility
        - Conversion from Laparoscopic to Open
    - Make middle initial and zip code mandatory
    - *Race to follow CMS 2728 form (White, Black or African American, American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander)
    - *Ethnicity (Not Hispanic or Latino, Hispanic or Latino)
    - *Remove 'unknown' option for the following items:
        - Vascular complications requiring intervention (KI & LI donors)
        - Other complications requiring intervention (KI & LI donors)
        - Biliary complications (LI donors)

- *Delete*
    - Post-op height
    - Did recovery and transplant happen at same center?
    - Kidney biopsy
    - Glomerulosclerosis
    - HIV-clinical disease, HIV-screening, HIV-confirmation, CMV-clinical disease, CMV-culture, HBV-clinical disease, HDV (Delta Virus), HBV-liver histology, HCV-liver histology, HCV-Was there clinical disease?, EBV-EBV DNA, EBV-Was there clinical disease?

- **POC Review**

  The Transplant Administrators Committee expressed the same concerns that they expressed during discussion of the TCR and TRF forms. Their main concern was the ability of transplant centers to collect accurate information because of the lack of consistent definitions for some of the data elements. It was noted that the Living Donor Committee wants to keep these data elements on the LDR.

  The POC approved AHDMG recommendations, including the decision not to add dates for individual lab values to the LDR, and to keep marital status, highest educational level, and working for income questions on the form: 8 in favor, 0 opposed, and 0 abstentions.

  *The POC approved AHDMG recommendations: 6 in favor, 0 opposed, and 0 abstentions.

LIVING DONOR FOLLOW-UP (LDF) FORM

- *Add*
    - Dates for individual post-donation tests and measurements (weight, serum creatinine, blood pressure, bilirubin, SGOT/AST, SGPT/ALT, alkaline phosphatase, serum albumin, INR)
    - Health insurance questions:
        - Health insurance at time of follow-up
        - Type of health insurance
        - Insurance loss or denial
        - Type of insurance lost or denied
        - Reason for loss of insurance
    - ER or urgent care visits related to donation since last follow-up
    - Add for all organs (not just for lung donors):
        - Activity level
        - Chronic incisional pain
        - Treatment for chronic incisional pain
    - Maintenance dialysis (liver and kidney)
    - Date first dialized (liver and kidney)

- *Modify*
    - *Replace 6 month LDF with 3 month LDF (will need policy and bylaw change to implement)
- *Delete*
    - CAT scan, MRI, and Ultrasound

- **POC Review**

  There was some concern about what type of glucose testing was proposed, and the POC decided not to add it to the form until this is clarified. The Transplant Administrators Committee expressed the same concerns about the working for income questions as they had with the TCR, TRR, and LDR forms.

  The POC approved the AHDMG recommendations, including the decision to keep working for income questions on the form, not to add glucose to the form, and not to modify the kidney and liver complications status questions : 8 in favor, 0 opposed, and 0 abstentions.

*The POC approved AHDMG recommendations: 6 in favor, 0 opposed, and 0 abstentions.

DECEASED DONOR REGISTRATION (DDR) FORM

Data elements proposed for all organ donor DDR forms:

- *Add to existing forms*:
    - TB History
    - Chagas History
    - Type of Skin Cancer at Time of Procurement
    - Clinical Inection Confirmed
        - Confirmed Clinical Infection Source
    - Type of Intracranial Cancer at Time of Procurement
    - Type of Extracranial Cancer at Time of Procurement
    - Type of Left/Right Kidney Pump
    - Liver Machine Perfusion
        - Machine Type
    - Heart Machine Perfusion
    - Left/Right Lung Machine Perfusion
    - NAT Results (HIV, HTLV, HBV, HCV, Chagas, West Nile)
    - Serology Results (Chagas, West Nile)
    - Was Patient Declared Legally Brain Dead?
    - Was ABG (arterial blood gas) Done?
        - FiO2
        - PEEP
        - Ventilator Mode
    - HbA1c
    - *For DCD: Any Extracorporeal Support Given and How Long
    - *Left and Right Kidney Biopsy Type
    - *Left and Right Kidney Biopsy, Number Glomeruli Visualized
    - *Left and Right Kidney Biopsy, Interstitial Fibrosis (Grade)
    - *Left and Right Kidney Biopsy, Vascular Changes (Grade)
    - *Liver Biopsy Type
    - *Liver Biopsy, Fibrosis (Grade)
    - *Liver Biopsy, Portal Infiltrates (Grade)
    - *For DCD: If yes to Any Extracorporeal Support Given, Flow Rate

- *Modify existing forms*:
    - pCO2 (becomes child question of Was ABG Done)
    - Blood PH (becomes child question of Was ABG Done)

- Collect every 5 minutes between withdrawal of support and start of agonal phase (currently collected every 15 minutes)
  - Date, Time, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Blood Pressure, O2 Saturation
- Collect every 1 minute between start of agonal phase and cardiac death (currently collected every 5 minutes)
  - Date, Time, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Blood Pressure, O2 Saturation

- *Race to follow CMS 2728 form (White, Black or African American, American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander)
- *Ethnicity (Not Hispanic or Latino, Hispanic or Latino)

- *Delete from existing forms*:
  - Clinical Infection
    - Source
    - Confirmed by Culture
  - Estimated Warm Ischemic Time
  - Inotropic Dosage
  - Inotropic Dosage Units
  - Inotropic Dosage Duration
  - Three or More Inotropes at Time of Incision
  - Was pO2 Done?
  - *Liver Biopsy, Other Histology
  - *Anticonvulsants

- **POC Review**

  The POC approved the AHDMG recommendations, including the decision not to add items about CMV IgG, CMV IgM, and donor travel history outside the US within the past five years.: 8 in favor, 0 opposed, and 0 abstentions. They disagreed with the AHDMG and voted to modify the collection of serial data on blood pressure and 02 saturation.

  *The POC approved AHDMG recommendations: 7 in favor, 0 opposed, and 0 abstentions.

Data elements proposed for all Pancreas and Liver donor DDR forms:

- *Add to existing forms*:
  - Volume of Initial Flush Solution

- Volume of Back Table Flush Solution

- **POC Review**

  The POC approved the AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

NEW EXPLANT PATHOLOGY FORM FOR LIVER RECIPIENTS

The first two questions on the form must be answered for *all* liver recipients:

- Was evidence of HCC found in the explant?
- Pre-transplant treatment for HCC?

If "No" is answered to both questions, the form is complete. Otherwise, additional information is requested:

- Number of tumors
- Satellite lesions?
- Tumor size, location, necrosis for each tumor
- Worst tumor differentiation
- Vascular invasion
- Lymph node involvement
- Other extrahepatic spread

- **POC Review**

  The POC agreed with the AHDMG recommendation to approve this new form: 8 in favor, 0 opposed, and 0 abstentions.

HISTOCOMPATIBILITY (HF) FORM

Data elements proposed on <u>Donor HF</u>:

- *Delete*:
    - Haplotype Match for Living Donor Recipients

- **POC Review**

  The POC agreed with the AHDMG recommendations: 8 in favor, 0 opposed, and 0 abstentions.

Data elements proposed on <u>Recipient HF</u>:

- *Add*:
    - <u>Anti-HLA antibodies:</u>
        - Were any HLA antibodies detected by Cytotoxicity? (Yes, No, Not Done)
        - Were any HLA antibodies detected by Solid Phase? (Yes, No, Not Done)
        - Was there current donor specific HLA antibody? (Yes, No, Unknown)
        - Was there historical donor specific HLA antibody? (Yes, No, Unknown)
    - <u>Crossmatch:</u>
        - Cell source
        - Which crossmatch tests were performed? (Cytotoxicity No AHG: Cytotoxicity AHG; Flow Cytometry; Solid Phase)
- *Delete*:
    - <u>Anti-HLA antibodies</u>
        - Most recent class I and II PRA/ HLA antibody screening:
            - serum date
            - target
            - technique
            - technique, specify
            - technique measures
            - anti-HLA interpretation
        - Peak class I and class II PRA/ HLA antibody screening:
            - serum date
            - target
            - technique
            - technique, specify

        - technique measures
        - anti-HLA interpretation
    - Was serum screened for anti-HLA class II antibody?
    - Were any sera tested pre-transplant that contain anti-HLA Class I antibody?
    - Were any sera tested pre-transplant that contain anti-HLA Class II antibody?
- Crossmatch:
    - Most recent crossmatch (for up to 5 crossmatches):
        - cell type
        - target
        - technique
        - technique, specify
        - measures
    - Date of crossmatch serum - least recent
    - Positive crossmatch with sera other than the most recent by any method (for 5 crossmatches):
        - serum date
        - cell type
        - target
        - technique
        - technique, specify
        - measures
- Donor retyping:
    - target cell source class I
    - target cell source class II

- **POC Review**

  The POC agreed with the AHDMG recommendations, including the decision not to delete items about crossmatch results and PRA values: 8 in favor, 0 opposed, and 0 abstentions.

Recommendations

Summary

The United Network for Organ Sharing (UNOS), as the Organ Procurement and Transplantation Network (OPTN) contractor for the Health Resources and Services Administration (HRSA) undertook a process to develop recommendations for cardiovascular related data elements to be collected on kidney transplant candidates and recipients. The purpose of this process was to inform the development of actionable, evidence-based recommendations for the addition of cardiovascular data elements to the OPTN dataset that meet one or more of the OPTN principles of data collection (Table 1).

In November 2009, UNOS convened a panel of experts in the fields of nephrology and cardiology to discuss an evidence review of selected cardiovascular data elements (Appendix A). We are indebted to the generous time contributions of the panelists: William F. Armstrong, MD; William M. McClellan, MD; Kenneth Jamerson, MD; Edward R. Garrity, Jr., MD, MBA; Michael Ragosta, III, MD; Bertram L. Kasiske, MD; Matthew R. Weir, MD; and Kenneth A. Andreoni, MD. Following the panelists' discussion, we administered two surveys using a modified Delphi approach. Panelists were asked to respond to several questions (Appendix B) for each data element in the first round of the Delphi survey. We reduced the survey questions to limit response burden for the second Delphi survey.

Based on the panelists' discussion and the responses to the two surveys, the following cardiovascular data elements emerged as strongly supported for collection by the OPTN.

- Ejection Fraction
- Cardiac Interventions
- Cardiac Troponin T
- Peripheral Vascular Disease
- Tobacco Use

The following elements were moderately supported, or were strongly supported by some but only marginally supported by others.

- Electrocardiographic Factors*
- Cholesterol*
- Atrial Fibrillation*
- Use/Duration of Beta Blockers*
- Hypertension

Finally, the following indicators were not well supported.

- Endothelial Dysfunction*
- Hemoglobin*
- Brain Nautrietic Peptide*
- Sleep Apnea

**Factor not included in the original evidence review.*

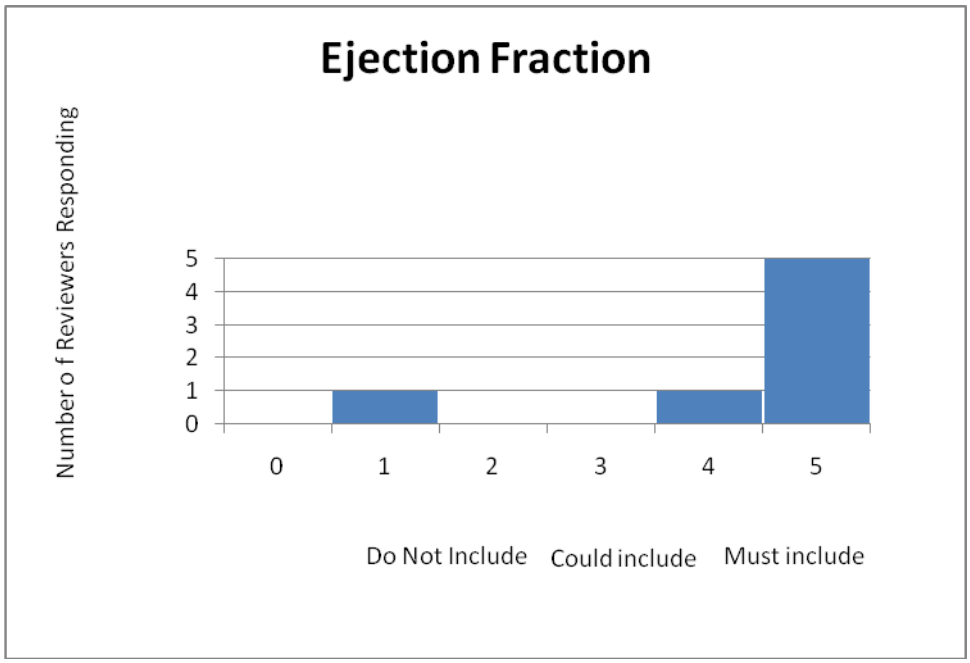
These recommendations are being provided to the Ad Hoc Data Management Group (ADDMG) for consideration during its deliberations about which data elements to propose for collection by the OPTN. In the remainder of the report, we provide additional details from the discussion and supplemental comments provided for each of the strongly supported and moderately supported data elements.

Strongly Supported Data Elements

Ejection Fraction (EF)

Overall Recommendation

The majority of the expert panelists agreed that ejection fraction (EF) should be collected at time of listing.

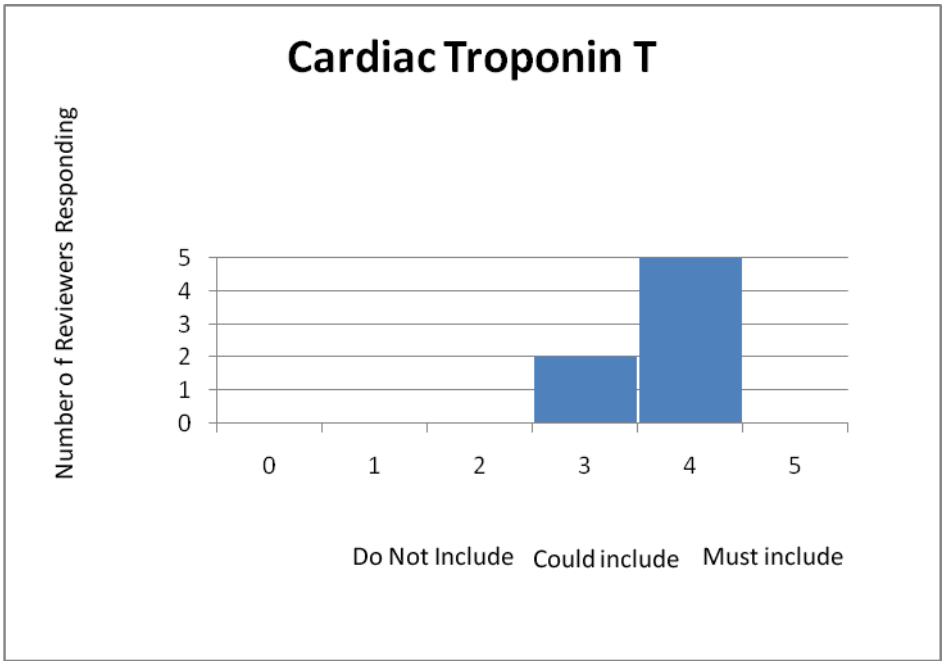


Data Collection

The experts explained that obtaining EF is currently not the standard of care for all transplant candidates. Candidates who do not have other evidence of cardiac disease usually do not undergo EF testing. Therefore, availability of this factor for all candidates would be limited. For candidates who undergo testing, the type of technology used to obtain the EF values do not appear to overtly influence the results so there should not be a need to collect the type of instrument or protocol used to obtain the EF values. The experts recommended that EF should be collected as a continuous variable.

Cardiac Troponin-T (cTnT)

All of the experts indicated that cardiac troponin-t (cTnT) could be collected at time of listing for kidney transplant candidates and at time of transplant for recipients.

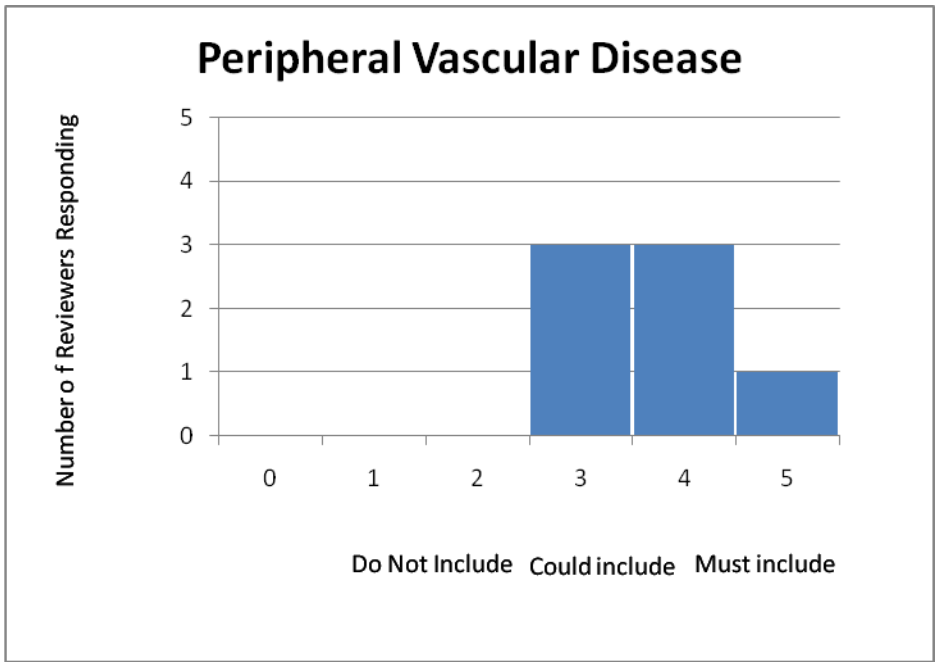


Data Collection

While cTnT is easily acquired, it is not routinely collected for all kidney transplant candidates, though its use was reported to be increasing. For candidates who undergo testing, the type of technology used to obtain the cTnT values do not appear to overtly influence the results so there should not be a need to collect the type of assay used. If cTnT were to be collected by the OPTN, the panelists recommended collecting it as a continuous variable.

Peripheral Vascular Disease

All of the panelists agreed that peripheral vascular disease (PVD) should be or must be included in the OPTN dataset.

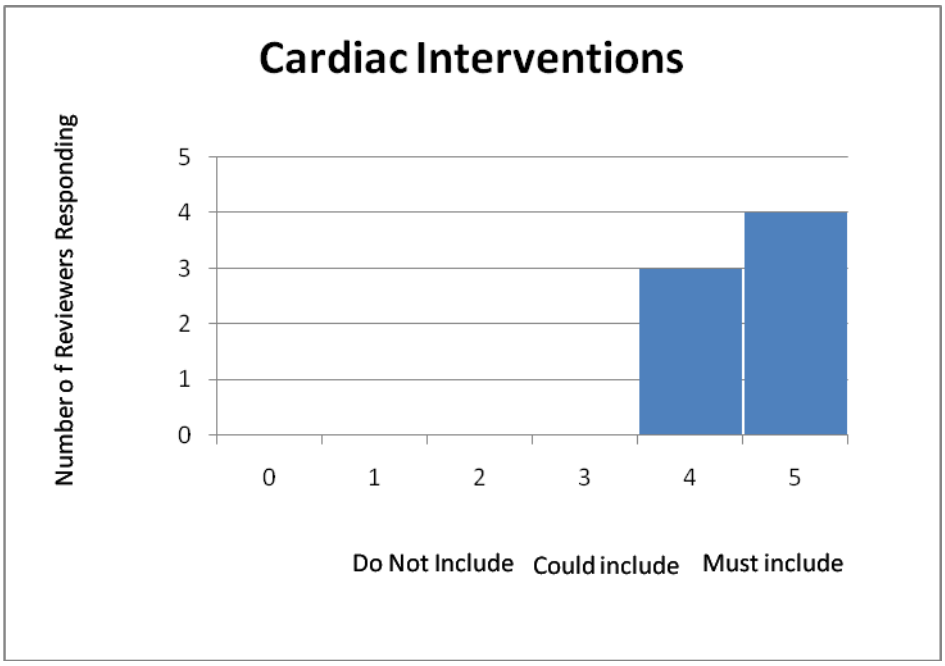


Data Collection

While the panelists agreed that PVD is an important predictor of waiting list and recipient mortality, they did not reach consensus on the most effective way to collect this information. As a diagnostic test, some panelists recommended collection of Doppler readings. Others recommended collection of interventions for PVD (e.g., amputation, peripheral bypass). Specific recommendations for the interventions to be collected were not defined by the panel; however other constituent groups including the American Society for Transplantation and the OPTN/UNOS Kidney Transplantation Committee have provided concrete recommendations.

Cardiac Interventions

The collection of cardiac interventions was the most strongly supported by all of the panelists.

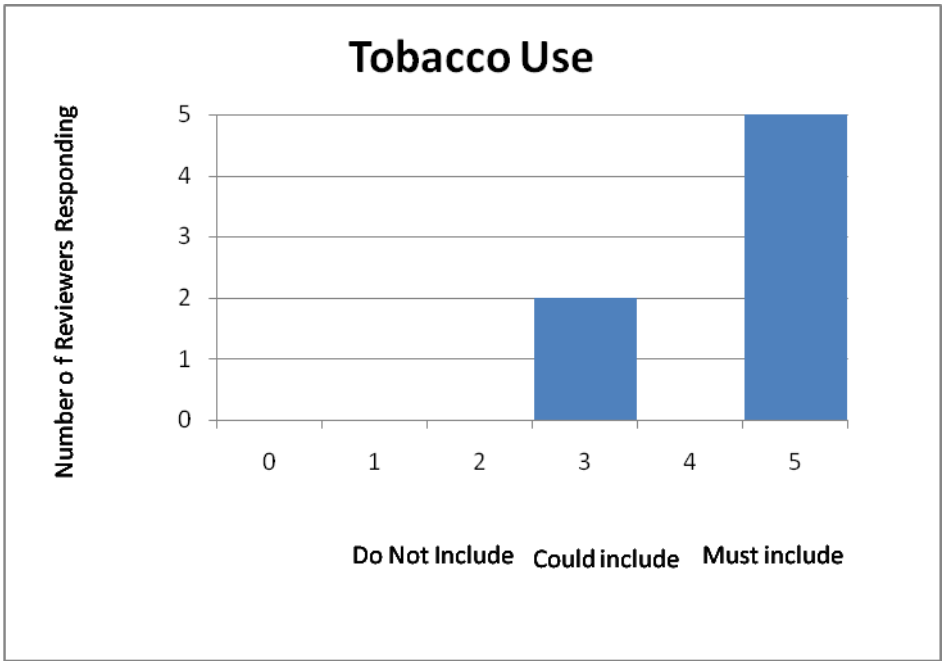


Data Collection

The panelists recommended collecting cardiac interventions as a categorical variable with distinct and clear interventions as options. Multiple selections should be permitted. Specific recommendations for the interventions to be collected were not defined by the panel; however other constituent groups including the American Society for Transplantation and the OPTN/UNOS Kidney Transplantation Committee have provided concrete recommendations.

Tobacco Use

The majority of panelists ranked Tobacco Use as a data element that must be included in the OPTN data set. The remaining panelists indicated that this data element could be included.



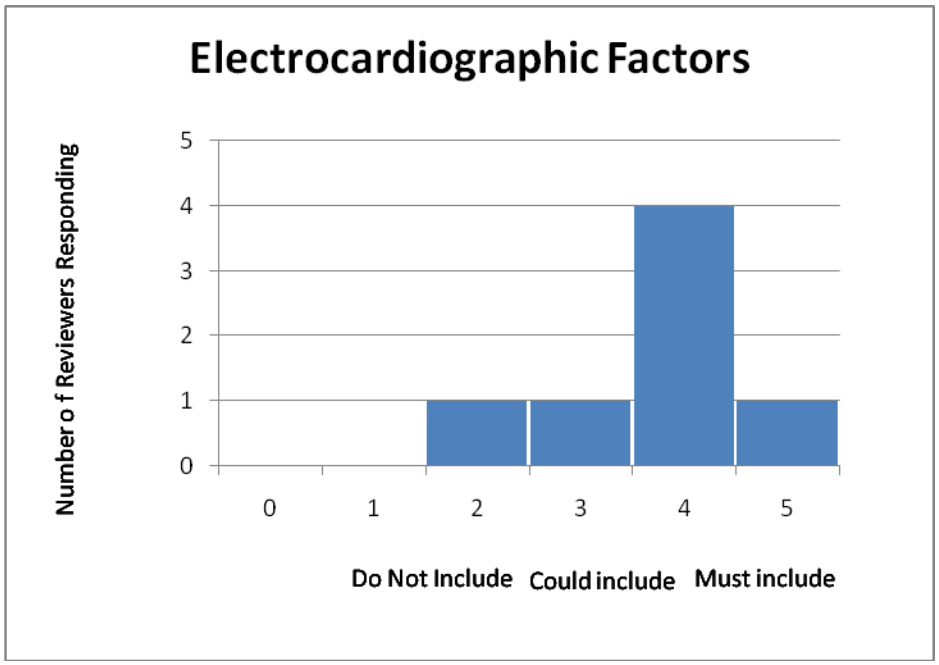
Data Collection

Tobacco use is currently used in other mortality and morbidity prediction models such as the Framingham Heart Study. The Centers for Disease Control and Prevention recommend collecting tobacco use as pack years. A pack year is defined as the equivalent of smoking 1 pack of cigarettes per day for a year. Pack years is calculated by multiplying the number of years smoked by the number of packs per day.

Moderately Supported Data Elements

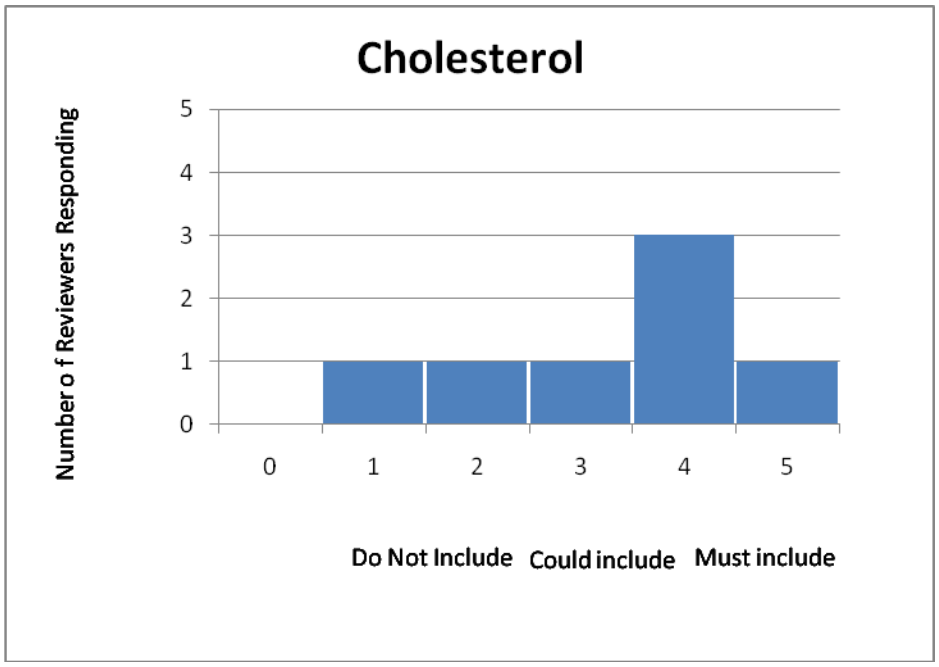
Electrocardiographic Factors

During the discussion the panelists shared that electrocardiograms are generally obtained for all transplant candidates and that collection of this information would be more objective than some other factors (e.g., tobacco use). However, there did not appear to be consensus over how to collect this information. Recommendations ranged from collection of a clinical diagnosis of left ventricular hypertrophy to measures of posterior wall thickness.



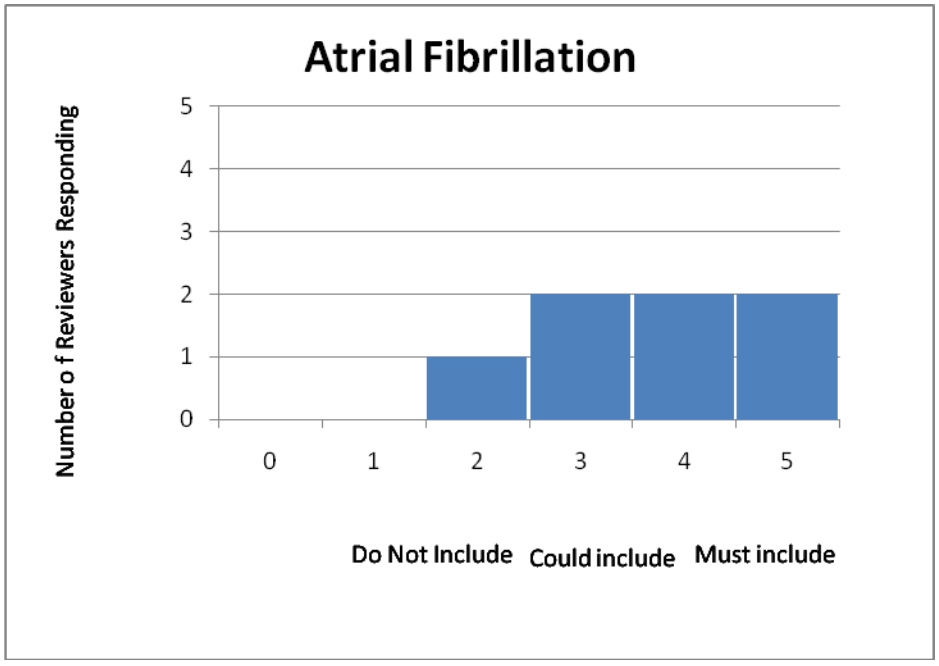
Cholesterol

Support for the collection of cholesterol was mixed amongst the panelists. While cholesterol is included in other morbidity/mortality models, such as the Framingham Heart Study, the panelists remarked that many factors can influence cholesterol levels including the use of statins and dialysis. Some panelists remarked that there would be a need for a uniform lipid panel and standards for collection. There did not appear to be an agreement on how to collect cholesterol in a meaningful way.



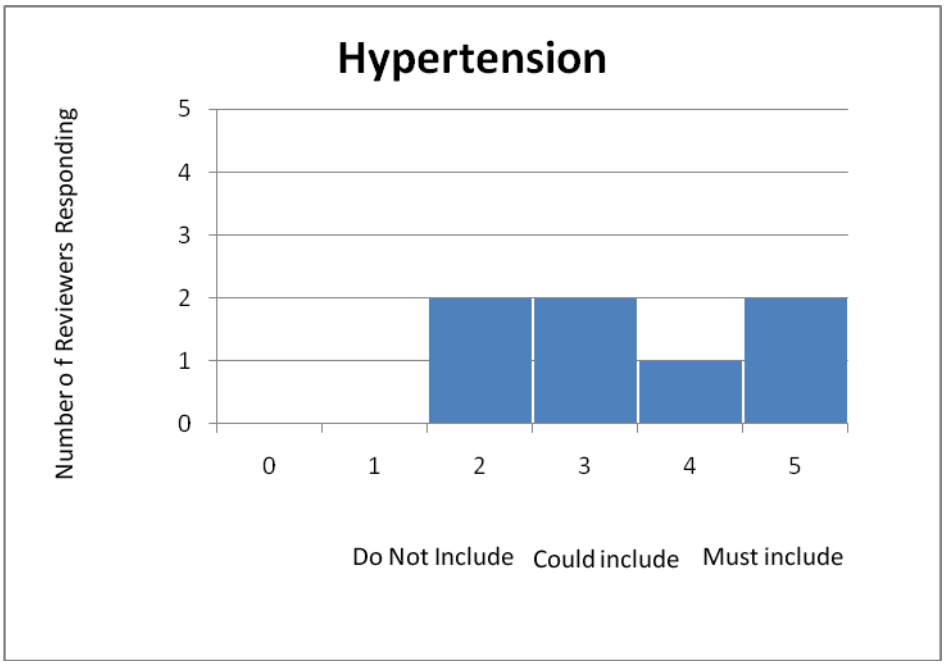
Atrial Fibrillation

During the discussion, a panelist suggested that presence of atrial fibrillation during the post-operative period for transplant recipients would be an important mortality predictor. While it was thought to be a likely predictor, collecting this information in a meaningful way on transplant recipients would be difficult (e.g., when to collect presence of atrial fibrillation following transplant). The panelists also remarked that atrial fibrillation was not an independent predictor and is associated with other variables such as coronary artery disease, poor volume control, and hypertension.



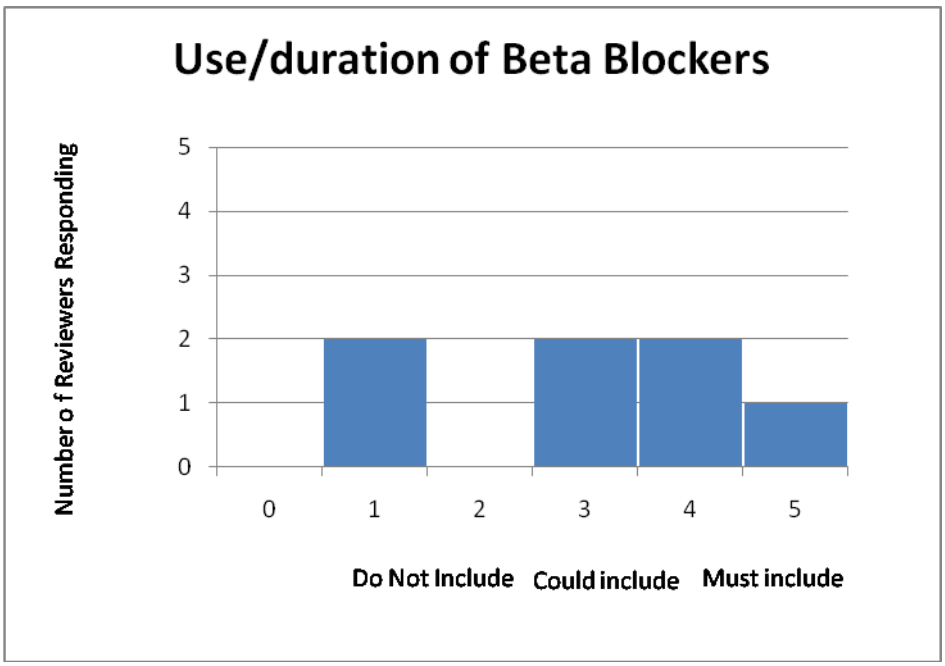
Hypertension

During the discussion, panelists remarked that the practical collection of hypertension would be difficult. Many factors affect blood pressure readings including method of collection, timing of collection, and the circumstances leading up to collection. Given that the OPTN collects this information at discrete time points (at listing, at transplant, and annually thereafter), the panelists did not agree that hypertension would provide meaningful predictive value.



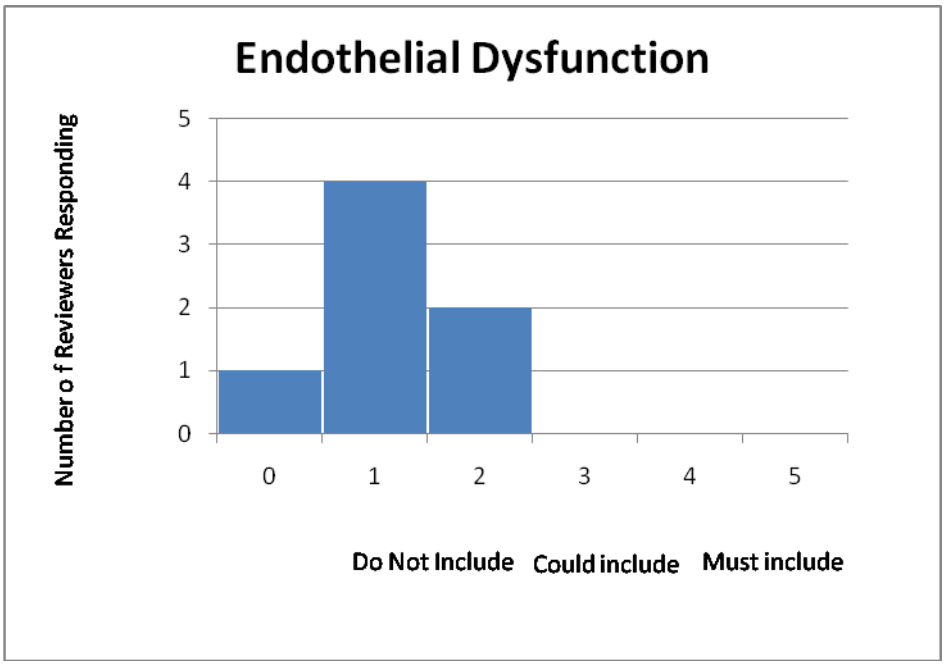
Use/Duration of Beta Blockers

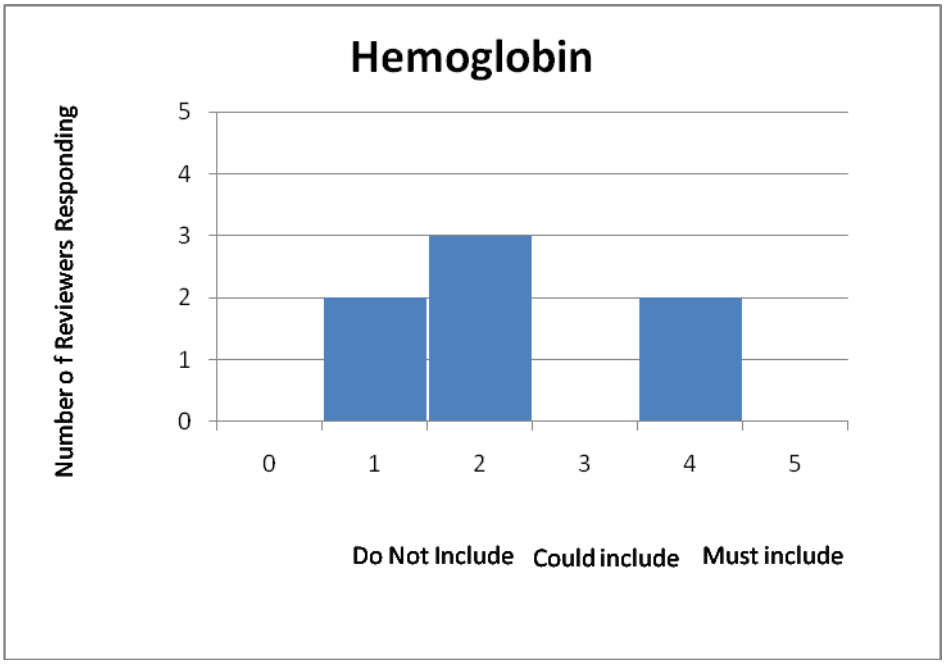
During the discussion, a panelist shared that during the perioperative period, beta blockers are frequently administered to recipients who are thought to be at immediate or high risk for cardiovascular event. Other panelists shared that it's not only the administration of beta blockers, but the duration for which they are administered. Some panelists remarked that practical collection of this information may be difficult and it would be difficult to differentiate between recipients who received beta blockers perioperatively from those who were on longer term beta blocker therapy. Support for collection of beta blocker use/duration was mixed.

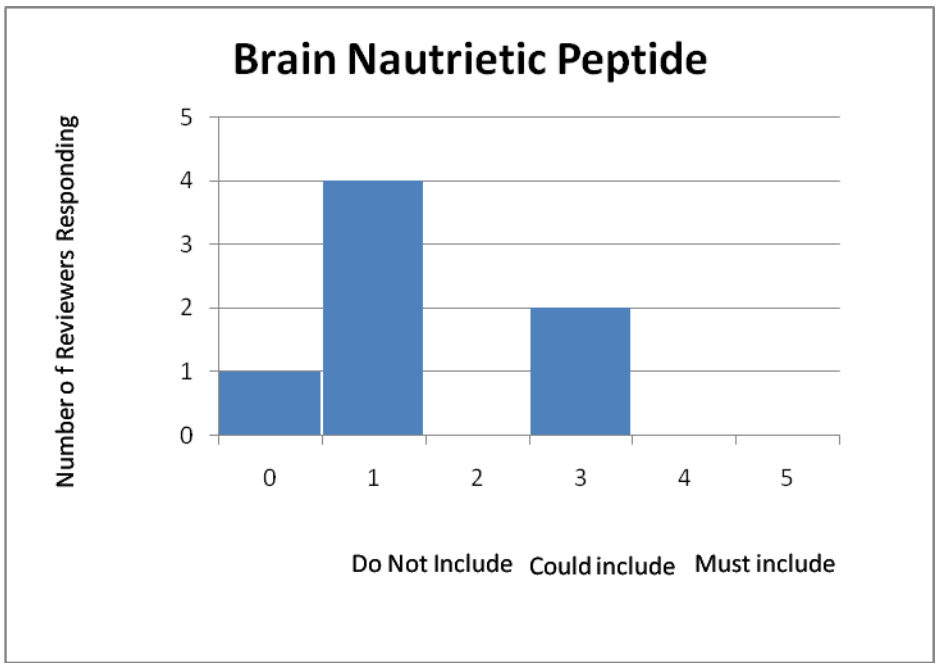


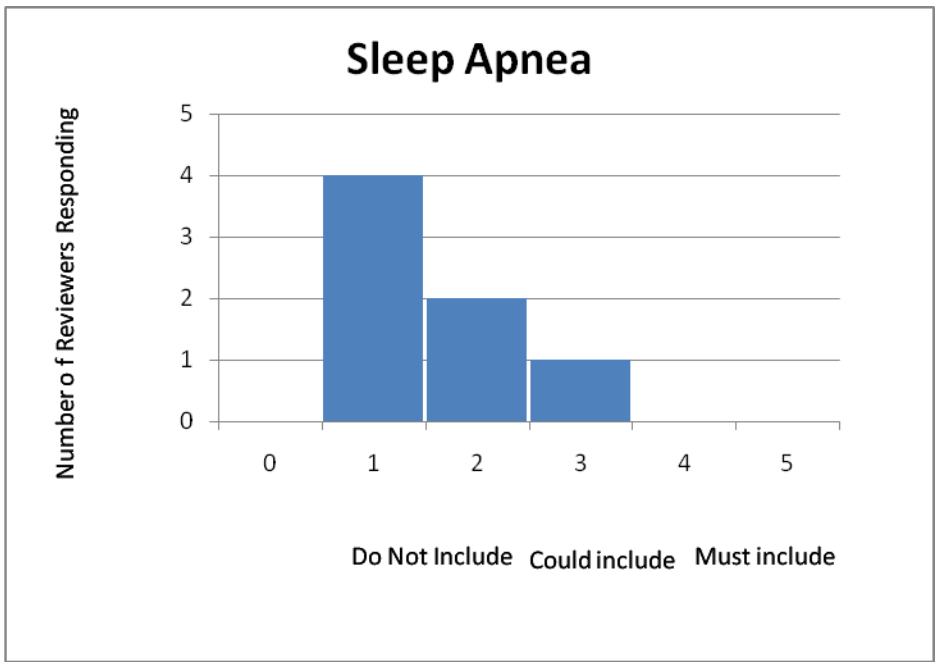
Unsupported Data Elements

Endothelial dysfunction, hemoglobin, brain nautrietic peptide, and sleep apnea were not supported as data elements to be collected by the OPTN.






Brain Nautrietic Peptide
Number o f Reviewers Responding
5
4
3
2
1
0
0
1
2
3
4
5
Do Not Include
Could include
Must include


Sleep Apnea
Number o f Reviewers Responding
5
4
3
2
1
0
0
1
2
3
4
5
Do Not Include
Could include
Must include