OPTN/UNOS Transplant Administrators Committee Report to the Board of Directors June 21-22, 2010 Richmond, VA

SUMMARY

I. Action Items for Board Consideration:

• None

II. Other Significant Items:

- The Committee partnered with the Living Donor Committee to administer the Living Donor Follow–Up Practices Survey. This survey was developed to study how individual transplant programs conduct follow-up with their living donors after donation surgery. (Item 1, Page 4)
- The Committee continues to support various committee Work Groups by providing the transplant administrator perspective on proposals prior to being released for public comment. (Item 1, Page 6)
- The Committee will continue developing DonorNet® educational tools for the transplant community. (Item 1, Page 6)
- The Committee reviewed and made recommendations for the OMB Data Collection Forms Review. These recommendations were submitted to the Ad Hoc Data Management Group (AHDMG) and the Policy Oversight Committee (POC) for consideration. (Item 2, Page 7)
- The 2010 Transplant Management Forum was held in Orlando, FL on April 21-23. (Item 4, Page 8)



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Gene E. Ridolfi, BA, RN, Chair Timothy J. Stevens, RN, BSN, CCTC, Vice Chair

The Committee meets monthly by conference call/Live Meeting except in April, when the Transplant Management Forum occurs, and July and October when the Committee meets in person.

- 1. <u>Committee Goals</u> The Committee continues to devote considerable time to working on four goals that were approved by OPTN/UNOS President James Wynn, MD. Those goals are:
 - <u>To provide input regarding all proposals with potential to impact transplant program</u> operations, and particularly with regard to: Member and patient communications regarding a new kidney allocation system and the OPTN kidney paired donation program; and Proposed revisions to living donor data submission policies and forms.</u> The Committee received an update on the Kidney Paired Donation (KPD) pilot program on March 24, 2010 via Live Meeting. The following questions and responses were discussed:
 - 1. Who will establish the financial model for the KPD pilot program? There will not be a financial model set by UNOS; however, there is a KPD Financial Subcommittee that is discussing the financial barriers to KPD
 - 2. Will kidneys be transported or will the donors? Each donor will indicate where they are willing to travel and each candidate will indicate if they are willing to accept a shipped kidney. Candidates that are not willing to accept a shipped kidney will only be matched to donors that are willing to travel to their center. In cases where the donor is willing to travel or the kidney is shipped, it will be up to the center to decide the best path forward, which is the current process
 - 3. How will transplant center indemnification be handled? This will remain in the purview of the centers involved. Some areas already have developed contracts and that contract language differs
 - 4. Will contracts need to be established between matching centers? This will depend on the requirements of each institution. The most common practice is that centers are having patients sign medical release forms with other centers in the KPD program
 - 5. Will there be only straight matches or will the pilot include open chains? Currently only two-way and three-way matches are included in the pilot
 - 6. Who will be facilitating match offers, coordinating efforts, etc. for exchanges? The actual match runs will always be generated at UNOS. The coordinating center will help with the logistics of the paired exchanges. One of the primary reasons this is a pilot is to determine the level of effort required to coordinate matches, the amount of coordination incorporated in a system, and the amount of manual centralized coordination that is necessary

The Committee had some suggestions regarding the KPD pilot program including developing standardized contractual language for centers to utilize and that a CMS representative become involved with the KPD pilot program to weigh in on cost reporting and other financial issues that may arise related to KPD. This same request was also raised on the KPD Finance

Subcommittee conference call on April 14, 2010. There will continue to be a Transplant Administrator Committee (TAC) KPD Work Group representative, and there will also be a TAC representative on the KPD Finance Subcommittee. These two representatives will report any updates on KPD to the Committee during the monthly conference calls and inperson meetings.

The Committee also provided feedback to the Living Donor Committee (LDC) regarding the LDC the Follow–Up Practices Survey and proposals that were released for public comment.

On December 8, 2010, the Living Donor Committee requested that the Transplant Administrators Committee help identify initiatives that would provide financial coverage for living donor follow-up for submission of follow-up data. The Living Donor Committee requested that the TAC identify best practice, and/or to identify existing impediments to obtaining living donor follow-up.

The TAC's response to the LDC's request described below was submitted to the LDC for consideration on February 22, 2010.

A small workgroup was formed to review the Living Donor Committee's request and to formulate the potential actions to address these key issues. The Committee suggests the following:

Identify initiatives that would provide financial coverage for living donor follow-up

- Solicit grants for funding of future donor complications
- Enlist the assistance of HRSA to engage CMS in discussions regarding the addition of Living Donor follow-up on the Medicare Cost Report
- Evaluate only Living Donors with their own personal healthcare coverage for any long term needs which may occur
- Evaluate only Living Donors with proof of US citizenship
- Negotiate with payers for improved coverage of living donation and the required 2 year follow-up costs

Identify what is considered best practice and/or to identify existing impediments to obtaining living donor follow-up

- Offer Saturday follow-up appointments to Living Donors. This would be for those donors who are employed as this currently tends to be a barrier to follow-up
- It may be more effective to provide focused education during the evaluation phase to the living donors on the requirement of 2 years of follow-up with the transplant center
- Providing the donor with just a statement or having the donor sign a form in the evaluation phase may not be the most effective means of communicating the importance of living donor follow up to the donor
- Explore state and/or federal income tax incentives (deductions) for living donors that comply with the 2 year follow-up requirement. This might help with the donor's reluctance to maintain the follow-up
- Explore ways to obtain Medicare economic support to transplant centers for living donation (Currently, this is an unfunded mandate for the transplant centers)
- Require transplant center social workers to do reminder calls to living donors when the next follow-up appointment is imminent (Increased time constraints on the Nurse Coordinators do not allow for focused reminders to donors)

Any of the above suggestions for improved financial coverage and overcoming the existing barriers to obtaining living donor follow-up for two years will not be easy tasks.

The Committee reviewed the LD Follow–Up Practices Survey on February 24, 2010. This survey was developed to learn more about how individual transplant programs conduct follow-up with their living donors after donation surgery. The goal of the survey was to learn what transplant programs see as their strengths and weaknesses in monitoring living donors over time. The Committee approved the survey and agreed to co-sponsor and promote completion of the survey within the transplant community. The survey opened March 12, 2010, and the results are currently being reviewed by the LDC. Once the LDC has reviewed the results of the survey, they will be shared with the TAC.

The Committee also supported the LDC by posting various items on the Transplant Administrators' Listserv.

The LDC requested that the Transplant Management Forum (TMF) have living donor breakout sessions and several living donor sessions were added to the 2010 TMF agenda. The TAC crossover member has continued to provide the Committee updates on current LDC activities/issues.

The Committee also discussed issues with compliance with the 24 hour wait list removal policy for all organs. The removal language is universal in all policies (Kidney 3.2.4.1, Thoracic 3.7.1.4, and Pancreas 3.8.7). Therefore, the Operations and Safety Committee was considering proposing multiple policy modifications. After reviewing the data, the Operations and Safety Committee decided to put any policy modifications on hold and review additional data in April. The data was presented to the TAC on November 18, 2009, and the TAC expressed some concerns regarding transplant centers ability to remain in compliance on weekends and holidays. The Operations and Safety Committee reviewed updated data at its meeting on April 15, 2010, and did not feel that this was a patient safety issue that needs to be addressed at this time. The TAC agreed with the Operations and Safety Committee's decision and no further action will be taken at this time.

The Committee also discussed the Proposal to change the Bylaws, to clarify the process for reporting changes in key personnel (Bylaw affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel) (Membership and Professional Standards Committee). The Committee recommends that the process be automated and that it is too repetitive. A conference call was arranged by MPSC liaisons with several TAC members to discuss the revisions to the proposal and to obtain further input. The Committee discussed this topic further at the October 2009 meeting and recommended that the MPSC consider that in 30 days of a change in key personnel, the transplant center will submit a transition plan and in 30 days will submit a permanent plan or have the opportunity to have more than one physician approved as a back-up. The Committee was asked to help develop a transplant administrator help book for UNOS compliance.

The Committee received a presentation on presented the new pancreas allocation system concept. The Committee posed some questions and concerns after the presentation, which will be communicated to and considered by the Pancreas Transplantation Committee prior to the proposal going out for public comment. On March 24, 2010, the Committee received a brief overview of a draft proposal for modifications to the vessel recovery, storage, and transplant policy that will be sponsored by the Operations and Safety Committee. The Operations and Safety Committee requested the TAC comment on the proposed modification to require transplant centers to report disposition of vessels via UNetsm within 3 working days of transplant or discard. The TAC suggested that the Operations and Safety Committee's Vessel Work Group discuss and disseminate best practices for vessel storage and compliance for the transplant centers to reference. Another concern the TAC raised was the impact this proposal will have on transplant center operations and workload.

On April 10, 2010, the TAC was requested to comment on a draft proposal for clarifying and improving policies on importing foreign deceased donor organs. The policies that would be affected by this proposal are 6.4.2 (Formal Protocol to Import Foreign Deceased Donor Organs) and 6.4.3 (Ad Hoc Import of Foreign Deceased Donor Organs). The Committee reviewed the proposal and has submitted its recommendations to the AHIR Committee for consideration.

The TAC also has representatives on other OPTN/UNOS committee Work Groups. Those Work Groups include: Policy Rewrite, Pancreas for Technical Reasons, Living Donor Bylaw, Living Donor, Patient Safety Review, the OPO's When Donor Data Changes, and Operations and Safety Vessel Policy. At this time, these TAC representatives participate in Live Meetings with these Work Groups to provide the transplant administrator perspective on proposals that evolve from the Work Group's sponsoring committees. These representatives are also responsible for reporting any Work Group updates and activities on the TAC monthly Live Meetings.

- To develop educational strategies for members regarding more effective use of DonorNet[®]. The DonorNet[®] Work Group continues to work on developing educational tools for the community. The Work Group has partnered with the Organ Procurement Organization Committee (OPO), AOPO, and the Transplant Coordinators Committee (TCC) to examine the use of non-standardized abbreviations, the documentation of donor information in DonorNet[®], and the use of varied training and orientation methods for new DonorNet[®] users. The Work Group submitted a data request to UNOS requesting examples of multiple abbreviation usage and inconsistent information entry within DonorNet[®]. There were numerous examples of incorrect information entered into DonorNet[®]. The Work Group requested that the OPO Committee review the data request results and provide feedback regarding next steps; suggestions on what should be included in the educational materials: and what is the best way to disseminate the educational materials to the transplant community. The TAC Work Group also requested that the OPO Committee consider if abbreviations in DonorNet[®] should eventually be eliminated. These same requests have been sent to AOPO's procurement directors for consideration. The OPO Committee formed a small working group to review the list of abbreviations. It is currently reviewing the draft abbreviations document and will provide the TAC with its recommendations at the end of May. Some possible educational tools include webinars, presentation at the 2011 TMF, and a DonorNet[®] Do's and Don'ts document.
- <u>To partner with appropriate committees and develop strategies for improved Wait List</u> <u>Management within transplant centers.</u> The TCC created and administered a survey on February 10, 2009, which was used to study real-world practices, timing, and communication related to listing and managing candidates at inactive status on the waitlist. It was the intent of the TCC to study the results and use them to help develop inactive waitlist management best practices. The TAC had three members that worked with the TCC on reviewing the results of the waitlist survey. The TCC is currently working on a publication for NATCO and presented the findings at the 2010 Transplant Management Forum in a breakout session.

- <u>Long Term Goal: To work with staff to develop potential strategies for improving the quality</u> <u>of data submission</u>. The Committee will provide ideas regarding improving program specific reports by discussing concerns with the program specific reports and ideas to address those concerns.
- Continued Goal: To partner with AOPO to define and disseminate best practices for flight standards and insurance. The OPO/Transplant Center Transportation Safety Work Group was charged with creating and administering a survey for OPO's and Primary Program Administrators that evaluates best practices for transportation and insurance with respect to organ recoveries. The Work Group had several conference calls with AOPO and per, AOPO's suggestion, consulted with Dr. Michael Englesbe, Assistant Professor of Surgery, Division of Transplantation at the University of Michigan Health System to develop the survey. UNOS has provided the transplant administrators' contact information from the UNOS database to the University of Michigan researchers to facilitate the survey process. The University of Michigan collected the results and presented them at a national meeting in March 2009 and they were published in the American Journal of Transplantation. James Cutler, CPTC, presented some of the important findings of the survey at the 2009 Transplant Management Forum in Seattle, WA on April 24, 2009, and provided an update at the 2010 Transplant Management Forum in Orlando, FL on April 23, 2010. The Work Group was considering the development of recommendations/guidelines for contractual relations between transplant centers and OPOs, but has decided to discontinue this project after lengthy discussions with the UNOS Senior Leadership Team.
- 2. <u>OMB Data Collection Forms Review</u> The Committee formed a Work Group to review OMB data collection forms including the Transplant Candidate Registration Form (TRR), Transplant Recipient Registration Form (TRR), Transplant Recipient Follow-up Form (TRF), Deceased Donor Registration Form (DDR), Living Donor Registration Form (LDR), and the Living Donor Follow-up Forms (LDF) via several conference calls. In summary, the Work Group recommended that for data entry efficiency, all fields identified by the data reduction effort of 2007 and 2008 for removal should be physically removed from the forms instead of just made optional. Since these optional fields are not entered consistently, they are of little or no value and only serve to make unnecessary work. The Work Group also recommended that the Malignancy form be removed in its entirety from the forms submission requirements. Transplant programs are ill-equipped to formally report malignancy data elements asked on the form. The appropriate source documentation for this form resides with the oncology staff, not with the transplant staff. Therefore, the Work Group recommended that, if these data are to be collected, a relationship between the American College of Surgeons and the National Tumor Registry could advantage that effort. All the pertinent information for the malignancy form is collected by the latter, and information from that Registry would be more accurate and robust than what transplant centers are able to provide. Also, transplant information systems vendors (e.g. HKS/Ottr) should be involved in early stages of the OMB forms change process so that they are apprised of upcoming changes enabling them to be better prepared to make concomitant changes to their software. The Work Group also noted that source documentation for data abstraction should be explicitly stated in the instructions and that specific definitions are given for all required fields. It would be helpful if the clinical relevance of the fields be described in the instructions to give the data abstractor a frame of reference. The TAC also recommended the addition of "History of Birth Control use" to the Living Donor Registration form and the addition of "Secondary/First Assistant Surgeon" to the Transplant Recipient Registration form. These recommendations were submitted to the Ad Hoc Data Management Group (AHDMG) and then to the Policy Oversight Committee (POC) for review. The AHDMG accepted the suggested additions of "History of

Birth Control use" and "Secondary/First Assistant Surgeon" and submitted these to the Policy Oversight Committee for consideration. The TAC also commented on the OMB data collection forms review during the public comment period.

- 3. <u>Program Review Work Group</u> This Work Group will focus on any OPTN requests the Committee receives. The Committee reviewed a MPSC memo requesting the assistance of various constituency committees to assist with the development of clear responsibilities and guidelines for individuals serving as a data coordinator and for feedback regarding if this position should be defined with the bylaws. Current bylaws provide similar information for clinical transplant coordinators, transplant pharmacists, and financial counselors; however, there are no descriptions for primary data coordinators. The Committee drafted a response and recommended that a OPTN/UNOS Task Force, consisting of representation of the MPSC, TAC, Transplant Coordinators, Histocompatibility Laboratories, and Organ Procurement Organizations (OPO) Committees, as well as UNOS staff to identify a data integrity model that can be recommended to the MPSC and the UNOS board for implementation. The final response was sent to MPSC on October 27, 2009.
- 4. <u>2010 Transplant Management Forum</u> The 2010 Transplant Management Forum was held April 21-23rd in Orlando, Florida. A total of 418 participants attended the meeting. The Committee accepted a total of 45 abstracts. There were 40 exhibitors, 9 sponsors and 6 abstract award sponsors supporting the meeting. The agenda included eight plenary sessions and four breakout session tracks. Evaluations of the meeting are pending. The 2011 Transplant Management Forum destination has not been selected at this time. The Committee has received several suggestions for 2011 sessions and the agenda planning will begin in July at the in person meeting in Chicago.
- 5. <u>Staffing Survey</u> The Committee continues to evaluate how the staffing survey might be helpful and useful for the MPSC as it evaluates new program applications or considers the performance of centers having outcome problems. The 2009 Staffing Survey was released on the Transplant Administrators section of the UNOS Secure Enterprise Web Site (<u>https://portal.unos.org</u>) in late February. Comparison statistics for transplant program staffing with the 2009 data are scheduled to be available to any member who has already submitted a survey by late May or early June. As in prior years, only programs that complete surveys for their organ specific programs will have access to the summary and comparison data. The goal for the 2009 Staffing Survey is to have 75% of all transplant programs complete the surveys in each organ specific grouping. In previous years, there was an increase in submissions in May and June, most likely due to exposure at the Forum. At the time of this writing, two weeks after the Forum, the responses from programs range from 7% for heart to 10% for kidney and liver programs. This represents a decrease of 8% to 10% response from the same period last year. A reminder notice was published in the January/February issue of the Update and there was also a notice posted in the April UNOS e-Newsletter to solicit more survey submissions.
- 6. <u>Request for Information Payer Work Group</u> The Committee continues to explore how the Request For Information (RFI) payer group could assist UNOS in understanding the perspective and concerns of the payer while balancing the needs of transplant centers for adequate reimbursement. The Work Group began working on 2010 updates at the July 2009 in- person meeting. Annual updates along with text revisions were submitted to UNOS. There were text changes on the readmission rate in section F, "Readmissions are any admissions to the transplanting center with 90 days from the transplant discharge date for any reason." The Work Group also suggested having UNOS add a text field where the individual adding an attachment can label the attachment. The Work Group provided UNOS staff with language providing

instructions on how to label the attachments. Another issue for the 2010 RFI was the list of Ventricular Assist Device (VADs) on the heart RFI. UNOS staff and the payer Work Group worked to develop acceptable updates to this list that were able to be accomplished within the 2010 RFI release schedule. Also, the Work Group discussed developing a FAQ document and field definitions. The 2010 RFI was released late- January 2010. In July, 2009, the chair for the payer relations Work Group met with Blue Distinction Centers for Transplants (BDCT) representatives in Chicago where they presented their request for RFI data in an electronic format. BDCT has requested to work with the TAC to set up an electronic transfer of data to prevent the need for manual entry for all concerned. The payer Work Group agreed that further exploration of the request of BDCT should occur. A meeting with BDCT occurred on October 16, 2009, in Chicago, IL. UNOS staff will work with the TAC and BDCT on developing a scope of work for this project. The next bi-annual UNOS Payer Relations meeting is July 2010, which solicits feedback from payers for RFI updates/improvements and provides payors with educational information.

7. <u>Public Comment Responses</u> – The Committee discussed and made recommendations for the following proposals released for public comment:

1. Proposal to Improve the Variance Appeal Process: Affected Policy: 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation) (Policy Oversight Committee)

Committee Response – The Committee reviewed and discussed the proposal to clarify and improve the variance appeal process. Members voted unanimously in support of this proposal (11- support, 0 - oppose, 0 abstentions).

2. Proposal to Add a Valuable Consideration Disclosure to the Bylaws Affected Bylaws: Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplantation (Living Donor Committee)

Committee Response – The Committee reviewed and discussed the proposal to add a valuable consideration disclosure to the Bylaws. The Committee did not take a formal vote on the proposal due to having the following concerns:

- The transplant center can't ensure understanding of the policy but they are able to inform the donor of the policy
- Will this require patient/donor signature
- How is compliance validated from a UNOS perspective
- How will this be handled for KPD across centers through national registries
- Can UNOS develop a flyer like the multi-listing flyer that can be included in the donor packet
- UNOS needs to begin considering the impact of creating new policies on the workload of transplant centers
- Legal counsel needs to address if there are any Federal legal implications to transplant centers and provide a statement back to the transplant centers
- Also, need to eliminate the signature for "understanding" clause

3. Proposed listing requirements for simultaneous liver-kidney transplant candidates Policy proposed: Policy 3.5.10 (Simultaneous Liver-Kidney Transplantation) (The Kidney Transplantation Committee and the Liver and Intestinal Organ Transplantation Committee)

Committee Response- The Committee supported this proposal. (12 support, 0 oppose, 0 abstentions)

4. Proposal to create regional distribution of livers for Status 1 liver candidates (Policy affected: 3.6 - Allocation of Livers) (Liver and Intestinal Organ Transplantation Committee)

Committee Response – The Committee unanimously opposed this proposal (0 support, 12 oppose, 0 abstentions). The Committee felt that this proposal creates organ access issues and the implications of this proposal need to be reviewed and further discussed. The Committee felt regional boundaries are just as arbitrary as OPO boundaries and should be based on distance.

5. Proposal to create regional distribution of livers for MELD/PELD candidates (Policy affected 3.6 - Allocation of Livers) (Liver and Intestinal Organ Transplantation Committee)

Committee Response – The Committee did not support this proposal (0 support, 12 oppose, 0 abstentions). The Committee felt that there needs to be more discussion and consideration of this proposal before making it policy.

6. Proposal to standardize MELD/PELD exception criteria and scores (Policy affected: 3.6.4.5 - Liver Candidates with Exceptional Cases) (Liver and Intestinal Organ Transplantation Committee)

Committee Response – The Committee supported this proposal (11 support, 0 opposed, 1 abstention).

 Proposal to add the factors "current bilirubin" and "change in bilirubin" to the lung allocation score (LAS) (Policy affected: 3.7.6.1 – Candidates Age 12 and Older) (Thoracic Organ Transplantation Committee)

Committee Response – The Committee supports this proposal. (12 support, 0 oppose, 0 abstentions)

8. Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors (Policy affected: 4.1.1 - Communication of Donor History) (Living Donor Committee)

Committee Response – The Committee supports this proposal (12 support, 0 oppose, 0 abstentions).

9. Proposal to change the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel (Bylaw affected: Appendix B, Section II, E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel) (Membership and Professional Standards Committee)

Committee Response - The Committee did not support the language of this proposal. The Committee felt that there needs to be more education provided to transplant centers on the process of reporting personnel changes. The Committee would like MPSC to consider allowing transplant centers the opportunity to provide a transition plan instead of having to notify of inactivity. (1 support, 7 oppose, 4 abstentions)

Proposal to clarify, reorganize and update OPTN policies on OPO and transplant center packaging, labeling and shipping practices (Policy affected: 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials) (Organ Procurement Organization (OPO) Committee)

Committee Response - The Committee considered the final disposition of vessels extremely important. They agreed that, whether vessels are transplanted or discarded, vessel outcomes should be reported to UNOS through the centralized data system and not through the OPO. If a transplant center accepts vessels with an organ and then does not transplant them into the patient but uses them on a different patient, the OPO has nothing to do with that transplant.

The Committee agreed that the "time out" should be clearly defined as it means different things to different ORs. (10 support with modifications, 0 oppose, 2 abstentions)

11. Proposed Modifications to Data Elements on the following Tiedi® forms1: 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 (Policy Oversight Committee)

Committee Response - On April 2, 2010, the Committee reviewed the "Proposed Modifications to Data Elements on Tiedi[®] Forms" public comment proposal. All members were encouraged to review the full proposal and provide individual comments as well. The TAC has had multiple conversations within the committee regarding this latest proposal and its impact on work load of the transplant center.

The Committee did not take a formal vote on the proposal but would like the following recommendations be considered:

• <u>Cost</u>

The TAC does not question the wisdom or importance of the proposed additional fields. However, it is the opinion of the Committee that the proposals are made with little deference to the transplant centers who must divert valuable and limited resources to collect and enter data, often directing resources away from the primary mission of caring for transplant patients.

The changes proposed add an average of 27 fields per form with the greatest volume of field additions in the TCR and TRR forms. It appears that much of the additional data fields are not proven predictors for measuring outcomes nor do they appear consistent with the guiding principles of OPTN data collection. Specifically, it appears that many of the additional data fields requested are not related to compliance, allocation, performance, or patient safety but rather at having potential value that has yet to be proven.

There is currently no method of reimbursement to the transplant center for the collection and submission of most of the data currently collected in addition to the new data elements being proposed. CMS does not reimburse via the Cost Report due to the fact that the majority of the data is related to post transplant care.

Transplant center resources are no different than any other organization. Centers are challenged with a shrinking bottom line which requires them to be conscientious stewards of their resources.

The Committee asked whether the financial burden of transplant data collection should be the sole responsibility of the transplant center. There must be other resource opportunities to support additional data collections in pursuit of research initiatives.

• **Documentation**

The OPTN data collection system has opportunities for improvement. The missing data reports generated by the SRTR bring this to bear. Transplant programs are already burdened with maintaining data quality and compliance with the OPTN and CMS regulations. Adding new fields will only exacerbate the problem.

To ensure consistency and accuracy across all programs, thorough and comprehensive documentation of all forms elements is mandatory. This includes specification of source documents and timing of data points. In addition to definitions, it is very useful to know the reason for collection of the element for contextual reference. A direct consequence of inadequate documentation is poor data quality and wasted time due to the necessity of trying to interpret instructions and tracking down data. This will translate to higher costs to transplant centers.

• <u>Drop Optional Fields</u>

The Committee recommends that only required elements should be on the forms. Optional elements should be removed because they are of questionable analytical value and waste data entry resources. Ethnicity and citizenship should be removed from the form due to the centers' inability to collect this information.

The Living Donor Committee is pursuing additional data directed at advocacy. Most centers are already struggling with trying to collect the current data requirement. The TAC does not support increasing the volume of unanswered or poorly answered questions and also continues to question the purpose of a five year follow-up period, particularly given that the SRTR only reports three year data post-transplantation.

<u>Suggestions/Recommendations</u>

- Do not increase the data requirement at this time
- Identify practices that would lead to improved reliability and validity of the data that is currently required
- Ensure that redundancy from one form to another is removed

- Ensure required forms would be programmed so that data points would auto-populate with each new form and reduce re-entering basic data requirements
- Ensure all fields have definitions and source documentation clearly identified so that data is consistent and remove center interpretation
- Provide a forum with CMS to discuss reimbursement for OPTN mandated data collection (including LD follow-up)

The TAC is in full support of doing the right work for their patients. Centers must also be fiscally responsible in challenging economic times. The TAC would also like to point out that the Committee has suggested further reductions, clarifications, and modifications of the existing data fields. The Committee asks that the POC re-consider those recommendations.

OPTN/UNOS Transplant Administrators Committee October 15-16, 2009 Chicago, IL

Committee Members in Attendance Gene E. Ridolfi BA, RN Timothy Stevens RN, BSN, CCTC Sharon Mathews NS, RN, CPTC Kim Barnett RN, BSN, CCTC Gary Sigle RN, MBA, BSN Pam Gillette MPH, RN Pamela Hester RN, BSN, CCTC David Hester Nancy Long RN, CCTC Nancy Metzler Janie Morrison FACHE Kimberly Nicoll RN, BSN James Cutler CPTC

Robert Walsh

Cassandra Smith-Fields RN, MBA, MSN

Committee Members Unable to Attend Mesmin Germain, MBA, MPH

Jacqueline Colleran

Staff in Attendance Angel Carroll MSW Cherri Carwile Jude Maghirang MS Lin McGaw, RN, Med

<u>Staff in Attendance via Conference Call</u> Sylvia Odom RN, MSN, NHS, CCTC Erma Edmiston Kerrie Cobb

Greg Levine

Chair Vice Chair Region 1 Representative Region 2 Representative Region 4 Representative Region 5 Representative Region 6 Representative Region 7 Representative Region 8 Representative Region 9 Representative Region 10 Representative Region 11 Representative At Large

Division of Transplantation, Ex Officio, non-voting Ex-officio

Division of Transplantation, Ex Officio, non-voting At Large

Liaison Assistant Liaison UNOS Staff Director of Professional Services

Region 3 Representative UNOS Travel Staff UNOS Staff

SRTR Liaison