

OPTN/UNOS OPO COMMITTEE REPORT SUMMARY

I. Action Items for Board Consideration

- None

II. Other Significant Issues

- The Board approved a change to the Bylaws, Appendix B to include the following criterion for both OPOs and Transplant Hospitals: Donation after Cardiac Death (DCD). OPOs/Transplant Hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors (Item 1, Page 3).
- The Board approved a modified list of Proposed Model Elements Required to be addressed in OPO and Transplant Hospital DCD Recovery Protocols [Joint OPO-MPSC DCD Protocol Development Work Group] (Item 2, Page 11).
- The Board approved the Proposed Modifications to Policy 7.0 (Data Submission Requirements) All imminent neurological, non-consented eligible and consent not recovered death notification information must be submitted by the OPO within 30 days of the date of the death notification. (Item 3, Page 15)
- A proposal was withdrawn from Board consideration regarding the Addition of Leprosy to the List of Exclusions to the OPTN Eligible Death Definition (The Committee withdrew this item from Board consideration at the December 13-14, 2006, meeting. Item 4, Page 19)
- Data Review, National DSA Dashboard. The Committee will form a work group to address how to best incorporate the National DSA Dashboard into the ongoing work of the committee. (Item 7, Page 25)
- OPTN/UNOS Report of Disease/Malignancy Transmissions, January 1- October 9, 2006. It was recommended that the Disease Transmission Advisory Group (Operations committee) develop an effective means of communicating this information and teaching best practices regarding patient safety and donor related disease/malignancy transmissions. (Item 9, Page 26)

The Committee will meet on February 28, 2007, and an amended board report will be included in the Board Book.

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**REPORT OF THE OPTN/UNOS ORGAN PROCUREMENT ORGANIZATION (OPO)
COMMITTEE TO THE BOARD OF DIRECTORS**

**St. Louis, MO
March 23, 2006**

**Charles Alexander, RN, MSN, Chair
Jeff Orłowski MS, CPTC, Vice Chair**

The following report represents the OPO Committee's deliberations since its June 2006 Board Report and includes proposals that were considered by the Board of Directors at its December 13-14, 2006 meeting. The information contained in this report regarding those items that have already been considered by the Board is included for documentation purposes. The Committee met in person October 17, 2006, in New Orleans, LA.

I. Action Items for Board Consideration

- None

II. Other Significant Issues

1. Bylaw Amendment Regarding Donation after Cardiac Death (DCD) Protocols for all Organ Procurement Organizations (OPOs) and Transplant Hospitals. At its April 5, 2006, meeting, the Committee reviewed an item referred by the Membership and Professional Standards Committee (MPSC) regarding the potential inclusion of Donation after Cardiac Death (DCD) protocols for transplant hospitals as a criterion for OPTN membership. The memo from the MPSC to the Committee noted that the April 2005 National Conference on Donation after Cardiac Death resulted in a number of recommendations regarding DCD practice and policy. One of the conference recommendations included the revision of transplant hospital and OPO membership criteria to require DCD protocols. The Board of Directors considered this recommendation during its March 2006 Strategic Planning Meeting; the Board asked the MPSC to discuss a potential addition to the Bylaws that would require OPTN members to submit their DCD protocols to the OPTN, and appropriate amendments to member applications.

At its March 2006 meeting, the MPSC determined that it was not appropriate to mandate that transplant hospitals have a DCD protocol and accept organs from DCD donors as a condition of membership. The MPSC requested that this issue be referred to the OPO Committee, and that the Committee consider the question of DCD related criteria for OPO membership in the OPTN. The MPSC also outlined the following discussion points and asked that the OPO Committee review and consider these points during its April 2006 meeting discussions:

Please note that comments from the OPO Committee are listed *in italic text* within or below the bulleted text of the MPSC discussion points.

There were some concerns expressed by the MPSC in its memo to the Committee regarding requiring the acceptance of DCD organs. The Committee discussed only a requirement for a protocol to facilitate recovery of DCD organs, not a requirement to accept DCD organs. (OPO Committee)

- Transplant Centers Hospitals should foster donation and the local transplant surgeons are encouraged to help the OPOs in that mission. (MPSC)
- Transplant Centers should take a leadership role in donation by working with OPO on DCD protocols.

Transplant Hospitals should take a leadership role in working with their local OPOs to establish a mutually agreed upon and cooperatively developed DCD protocol.

- It will be difficult to require DCD Protocols in transplant hospitals as the staff responsible for implementing the protocols are not the transplant team members.

The Committee did not see this as an obstacle to implementing a DCD protocol for organ recovery. Establishing a DCD protocol to facilitate the recovery of DCD organs will be the responsibility of the transplant hospital administration and the OPO, not the transplant team members.

- The Committee did not feel that the OPTN had any role with donor hospitals and pointed out that the OPTN has no jurisdiction over donor facilities.

The Committee agreed and noted that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is currently developing an accreditation requirement that all hospitals work with their local OPO to evaluate DCD potential and establish a DCD protocol where applicable. If approved and implemented by JCAHO, this requirement would address both donor and transplant hospitals. The Committee noted that with regard to OPOs and transplant hospitals, the OPTN should be the leader in supporting the development and implementation of protocols to facilitate DCD organ recovery.

- The DCD donor may not be housed in the transplant hospital, so the transplant hospital may not be the one who should bear the burden of developing protocols.

The transplant hospital may also be the donor hospital, and as such, the transplant hospital should lead the community by example and support DCD by having a protocol in place.

- Several MPSC members indicated that they could recover organs from a DCD donor in their hospital, but could not use the organs based on a determination by their hospital ethics board. Others noted that they were also bound their hospital regulations and could not accept DCD donor organs.

The OPO Committee's discussion and recommendation focus solely on DCD recovery protocols, not DCD organ acceptance or transplantation.

- OPOs should be encouraged to review their data regarding DCD donation.

Data review is essential to continuous improvement of practice for both OPOs and transplant hospitals.

- It was suggested that OPOs must have DCD policies in place, and that they actively place protocols in the hospitals within their DSAs. It was further noted that one protocol may not 'fit' every hospital.

In the Committee's discussion and recommendations, OPOs and transplant hospitals would both be required to have a DCD protocol. OPOs are expected to continue to work with individual hospitals within their DSAs to cooperatively develop hospital DCD protocols that work well for/with the hospital.

After discussion of the above issues, the Committee unanimously approved the following recommendation in response to the MPSC: ****RESOLVED**, that, by January 1, 2007, all OPTN member organizations be required to have protocols to facilitate the recovery of DCD organs. Vote: 12 For, 0 Against, 0 Abstentions.

Charles Alexander, RN, MSN, Committee Vice-Chair, joined the May 16-17, 2006, MPSC meeting via teleconference to present the Committee's proposal for and continue discussion on including DCD protocols as a criterion for OPTN membership. Mr. Alexander reported that the Committee responded to the concerns expressed by the MPSC (as outlined above.) Mr. Alexander discussed the idea of creating a work group with representation from programs with significant DCD experience; this work group would be charged with developing recommended standards for DCD protocols. He also noted that DCD protocols would be a future requirement for Association for Organ Procurement Organization (AOPO) accreditation.

Members of the MPSC expressed concern regarding moving forward to develop requirements for protocols to facilitate DCD organ recovery. It was noted by the MPSC that some hospitals have policies that prohibit DCD. The MPSC also noted the variability among transplant hospital ethics committees regarding positions on and perceptions of DCD. The MPSC also discussed the varying level of DCD experience within the transplant community, and that a recognized standardized protocol does not presently exist. Members of the MPSC opined that it is too early to develop a DCD requirement without addressing several critical points. For instance, the issues of what constitutes death and end-of-life care must be addressed. The MPSC agreed that requirements for DCD protocols as a condition of membership are premature.

The MPSC considered the need to establish a working group to address the following issues:

- Collect and use data from various available sources such as the Institute of Medicine (IOM) and recent national DCD Consensus Conference to outline the essential elements for an effective DCD protocol.
- Evaluate whether OPTN membership requirements regarding DCD protocols should be required or included only as guidance. Consider possible risk in directing hospitals in a manner that may conflict with their internal processes.
- Develop a communication plan for OPOs and Transplant Hospitals to address DCD protocols.

The MPSC agreed that the working group would convene under the auspices of the OPO Committee and consist of various stakeholders (i.e. HRSA Staff, Ethicist, Representation from the Organ Transplant Breakthrough Collaborative, Transplant Surgeons, and Patient Affairs Committee representation) from the transplant community. The purpose of the working group would be to educate the transplant community on current DCD protocols, develop a plan on how DCD protocols would be worked through the Ethics and Administrative Processes within hospitals, and create DCD standards to address key aspects (e.g. end-of-life care) for the transplant community. The MPSC agreed that the working group should work with the OPO community to ensure that OPOs collaborate with the hospitals within their Donor Service Area (DSA) on DCD protocols. MPSC members also discussed and agreed that it was very important for OPOs with DCD protocols in place to communicate their procedures to the hospitals within their DSA.

The MPSC encourages responsible efforts to recover and use more organs from DCD donors. In this light, the MPSC recommends that OPOs with existing DCD protocols review those protocols to ensure that appropriate oversight for the procedure is provided for and practiced. The MPSC further approved the following recommendation (modified from the original recommendation of the OPO Committee): ****RESOLVED**, that the Bylaws shall be amended to include the following criterion for both OPOs and Transplant Centers: Donation after Cardiac Death (DCD) Protocols. OPOs/Transplant Hospitals should develop by January 1, 2007 [and once developed must comply with*], protocols to facilitate the recovery of organs from DCD donors. The MPSC voted 23 For, 0 Against, 1 Abstentions.

*Following consideration of this proposal by the MPSC, it was noted that the Bylaws could be strengthened by including an express provision regarding compliance with DCD protocols. Suggested language is included in brackets.

Following presentation and discussion of the proposal at the June 2006 Board meeting, the Board approved a modified Bylaw amendment proposal for public comment distribution. The Board supported the intent of the proposal, and recognized that a Bylaw amendment requiring Donation after Cardiac Death protocols for all OPOs and transplant hospitals warrants both the discussion and vote of the transplant community and the public. The modified proposal submitted for public comment is as follows:

RESOLVED, that the Bylaws shall be amended and submitted for public comment, to include the following criterion for both OPOs and Transplant Centers:

Donation after Cardiac Death (DCD) Protocols. OPOs/Transplant Hospitals *must* develop by January 1, 2007 and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors.

The Board also directed the development of a bylaw modification to require in the interim (i.e. prior to an effective date of the foregoing bylaw amendments), that if an OPO recovers organs from a DCD donor, the OPO must follow an established protocol to recover such organs.

In addition, at its June 2006 meeting, the Board established a Joint OPO-MPSC (Membership and Professional Standards Committee) working group to develop essential standard elements to be addressed in a DCD recovery protocol. The Board agreed that the intent of developing DCD recovery protocol model elements is to establish general member standards for OPO and transplant hospital DCD recovery protocols. The DCD recovery protocol model elements

are intended to be a general outline of what to address, not how; the elements are not intended to be prescriptive, but rather established enough to offer guidance in developing a protocol, and flexible enough to allow for OPOs and transplant hospitals to work collaboratively within their DSAs to create a protocol that both meets membership standards and allows for variation in local practice.

The proposed DCD recovery protocol bylaw amendment was submitted for public comment from August to October 2006. The UNOS regions have, to date, voted unanimously in support of the proposal; the proposal has also received broad support from committees.

The Pediatric Transplantation Committee discussed the proposal and a letter submitted from a Boston Children's Hospital physician as part of public comment. The Pediatric Committee invited Charles Alexander, Committee Chair and Joint Working Group Chair, and Jeff Punch, MD, MPSC and Joint Working Group member, to join a November 9, 2006, Pediatric Committee conference call to discuss DCD recovery issues that specific to pediatric hospitals and pediatric populations.

The Pediatric Committee continued its discussion regarding the January 1, 2007, implementation of the revised JCAHO organ procurement and donation standard as well as related modifications proposed by the OPO Committee to Appendix B of the OPTN Bylaws that require hospitals to develop and then comply with a protocol regarding donation after cardiac death (DCD). Members reviewed a presentation outlining one free-standing pediatric center's experience in developing a DCD protocol over the last year. A letter sent to the Pediatric Committee outlining concerns related to the OPO Committee's proposal was also considered. There is concern within at least some segments of the pediatric intensivist community, which have not embraced these protocols as part of end of life care.

Patrick Healey MD, Chief of the Division of Transplantation, Children's Hospital and Regional Medical Center, Seattle, WA, and Pediatric Committee member, recounted his center's challenges in implementing this protocol during the public comment review call held on October 3, 2006. It was suggested that pediatric programs in general may have more difficulty in influencing the necessary hospital leadership to put such protocols into place. After consideration, the Pediatric Committee members participating in this call supported the proposal (5-0-0), but recommended the OPO Committee provide assistance, educational materials and example protocols from pediatric centers that already have protocols in place to help facilitate this process. The Pediatric Committee also requested information on the number of pediatric centers that now have protocols in place, and planned to discuss this further during its November 9, 2006, meeting. Mr. Charles Alexander, OPO Committee Chair, and Dr. Jeffrey Punch, a MPSC member who participated in the Joint Working Group that developed the proposal, participated in the Pediatric Committee's November 9, 2006, conference call to provide insight into the expectations of this proposal and answer any related questions.

During the November 9, 2006, teleconference, Dr. Healey shared further details regarding his center's experiences in a free-standing children's hospital developing a pediatric DCD protocol with a brief slide presentation during the teleconference. He emphasized the importance of addressing concerns from the intensivist community, where endorsement of this concept is essential. It was stressed that transparency of the process is very important, especially considering that most ICUs have their own processes for end of life care and withdrawal of support that may require adjustment to accommodate some of the standard DCD procedures. Dr. Healey recognized impediments to DCD to include:

- Hospital: Lack of protocols, or real interest
Physician and staff resistance
- OPO: Limited financial and staff resources
for outreach, education and technology
- Organs: Concerns about the quality of DCD organs
and utilization
- Ethics: Medical interventions
Termination of life-sustaining treatment
Determination of death

Dr. Healey did question whether pediatric DCD donor organs were being utilized for pediatric recipients, citing the data below:

2003 data	Total	<18 years of age
DCD donors	271	28
DCD kidney transplant recipients	394	9
DCD liver transplant recipients	114	5

**AJT 2005 (Pt 2) 887-903*

These data indicate that most pediatric DCD organs are transplanted into adult recipients. He also recognized that challenges specific to pediatric hospitals include: (1) low donor volumes, (2) low volume transplant, (3) may be both donor hospital and transplant center with low volumes, and (4) a best practice model has not yet been determined for DCD in children. He noted that this must first be looked at as an end of life issue, recognizing that if parents want to donate, it is a hospital's responsibility to find a way to meet the request. Dr. Healey reported that his center will have its protocol in place for the January 1, 2007, deadline, but recognized that it has taken approximately a year to complete the process.

The Pediatric Committee then reviewed a recent letter from a pediatric center reporting its concerns regarding the upcoming January 1, 2007 deadline for such protocols to be in place for transplant centers. Co-Chairs of this center's Task Force on DCD suggested that there are unique differences for pediatric patients and DCD that it feels have not been, and requested a delay in requiring such protocols for pediatric institutions. It was suggested that a national consensus conference on pediatric DCD be convened in the near future, where the by-law modifications might be reconsidered on the basis of evidence and opinion gathered at the conference.

A member noted his program has worked through a process similar to that shared by Dr. Healey, but has still not come to a consensus. Two issues continue to remain outstanding:

1. An ethical issue of whether a parent's or parents' decision to pursue DCD donation is in the best interest of the child. In the case of DCD, a child is still alive, unlike a standard criteria donor that is brain dead. Some see DCD as withdrawing care to the pediatric patient. Some ethicists participating in this center's working group could not resolve these concerns.
2. The position of the pediatric intensivists must also be considered. Though it may be an emotional response, many oppose the DCD donation process and an intrusion into a carefully developed process.

He related that discussion became very polarized when presenting a proposed DCD plan to the hospital's Board of Directors. He suggested the Pediatric Committee review the DCD requirements and consider their impact in the pediatric community.

Dr. Jeffrey Punch noted that pediatric DCD cases have been some of the most gratifying in his opinion, with families being most appreciative of an opportunity to bring hope to an always difficult situation. He suggested that there are no issues separating the pediatric and adult DCD process. Disagreeing with the ethical arguments noted in the letter, Punch suggested there should be no downside to DCD if you believe that it is ethical to withdraw care, a part of natural end of life care.

An intensivist on the Pediatric Committee recognized that DCD is an emotional issue, especially when dealing with pediatric death. He sees the response within this community as possible reaction against the upcoming requirements as mandatory. He noted consensus statements from the Institute of Medicine and the Society of Critical Care Medicine (SCCM) are frequently referenced within centers that are working to develop these protocols. It is important to recognize these statements are not based on pediatric medicine, as no best practice models for DCD have been developed for children. Members also voiced concerns that there are differences between pediatric and adult DCD, questioning whether measures to define death are the same for adults and children. It was noted that all current references are based on adults. After discussion, it was suggested this Committee make a recommendation regarding these practices, agreeing with the letter's recommendation of a pediatric conference on pediatric DCD to consider these issues in greater detail.

Members suggested that it should be the Pediatric Committee's role to take a lead in determining a position for pediatric organ donation by outlining components of a best practice model for DCD in children, noting that the other professional societies would look to the transplant community for guidance. Stuart Sweet MD, Medical Director of the Pediatric Lung Program at St. Louis Children's Hospital and Pediatric Committee Chair, agreed. He noted that the Pediatric Committee should support its goals to ensure that every child has his/her best opportunity for transplant and has a good post-transplant outcome by recognizing that DCD is in the best interest of the pediatric community- whether these organs go to a child or to an adult that may have been competing on the wait list with a child for an organ. Using this as a framework, he recognized the importance of partnering with other organizations who are taking the lead in moving DCD forward. As a result, he recommended that the Pediatric Committee support the upcoming DCD protocol requirements, recognizing that the pediatric transplant community tends to respond more slowly. It was suggested that programs unable to meet the January 1, 2007, deadline submit documentation detailing where they are in the process of meeting these requirements, as well as an interim plan for responding to families who wish to pursue DCD before such protocols are in place. It was noted that the JCAHO standard requires a policy be in place, not that DCD recoveries actually be performed.

As a result of these discussions, the Pediatric Committee will address its concerns to the Board of Directors during its December 2006 meeting with the following resolution:
** RESOLVED, that the Pediatric Transplantation Committee reinforces its support for the DCD protocol initiative, but requests that the Board and Membership and Professional Standards Committee recognize the unique challenges faced by pediatric hospitals in establishing these protocols. Therefore, the Committee requests that enforcement of the policy for transplant hospitals treating primarily pediatric patients be deferred as long as the hospital demonstrates ongoing progress toward establishing pediatric DCD protocols.

In addition to this request, the Pediatric Committee plans to respond to the letter of concerns and follow up the recommendation for a conference on these issues by enlisting support to include the topic on the agenda for an upcoming pediatric summit being planned to take place during the first half of 2007. It is expected that the meeting will already include a large number of pediatric intensivists, comprising an essential audience. The Pediatric Committee believes that this will further and constructively support the JCAHO and OPTN requirements for DCD protocols in all hospitals.

Mr. Alexander noted that the Joint OPO-MPSC Working Group that developed this proposal is in the final stages of producing model elements document for DCD policies as an outline of things that should be covered. Resources will be solicited from pediatric hospitals that have had greater experience with DCD recovery. He also noted data from summer 2005 through summer 2006 indicated that there were approximately 200 pediatric DCD organs recovered during this year calendar year. Ms. Jade Perdue, Health Resources and Services Administration, reported HRSA's Collaborative efforts have also focused on increasing DCD awareness and utilization for some time. She confirmed that the Collaborative would also be able to assist in circulating information regarding centers that excel at DCD recovery to share the experiences and protocols with other centers still in the developmental stages.

At the December 2006 Board meeting, the Board approved the following proposal: ****RESOLVED**, that the Bylaws, Appendix B shall be amended to include the following criterion for both OPOs and Transplant Hospitals, effective January 1, 2007. Effective March 30, 2007, these protocols must address the required model elements set forth in Attachment III to Appendix B of the Bylaws:

APPENDIX B TO BYLAWS OPTN

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

General. [NO CHANGES]

Key Personnel. [NO CHANGES]

Plan for Public Education on Organ Donation. [NO CHANGES]

Communication of Information for Organ Distribution. [NO CHANGES]

Donation after Cardiac Death: OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the required model elements set forth in Attachment III.

Note: the language set forth above in double underline shall be effective March 30, 2007.

II. Transplant Hospitals.

General. [NO CHANGES]

Survival Rates. [NO CHANGES]

Inactive Membership Status. [NO CHANGES]

Key Personnel. [NO CHANGES]

Clinical Transplant Coordinator. [NO CHANGES]

Financial Coordinator. [NO CHANGES]

Routine Referral Procedures. [NO CHANGES]

Designated Transplant Program Status. [NO CHANGES]

Donation after Cardiac Death. Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the required model elements set forth in Attachment III.

Note: the language set forth above in double underline shall be effective March 30, 2007.

2. Update on the Joint DCD Protocol Development Work Group. At the June 2006 Board meeting, in support of the HHS Program Goal to increase the number of DCD donors and in support of efforts in the donation and transplantation community, the Board unanimously approved the following two proposals:

OPO Committee proposal:

RESOLVED, that the Bylaws shall be amended and submitted for public comment, to include the following criterion for both OPOs and Transplant Centers: Donation after Cardiac Death (DCD) Protocols. OPOs/Transplant Hospitals must develop by January 1, 2007 [and once developed must comply with*], protocols to facilitate the recovery of organs from DCD donors. *Following consideration of this proposal by the MPSC, it was noted that the Bylaws could be strengthened by including express provisions regarding compliance with DCD protocols. Suggested language is included in brackets.

The above proposal is currently out for public comment and is scheduled to be reviewed by the Board at its December 2006 meeting.

Membership & Professional Standards Committee (MPSC) proposal:

RESOLVED, that a working group be created under the auspices of the OPO Committee to develop the important elements that must be addressed in protocols for DCD procurements and addressed by OPTN Members in developing such protocols.

Following the June 2006 Board meeting and the charge of the Board approved MPSC proposal, the DCD Protocol Development Work Group was formed. Charles Alexander, OPO Committee Chair, is serving as the Chair of this work group; the work group has both OPO and MPSC Committee representation. In the membership of this group, we have worked to include both surgeon and physician (including pediatric and critical care) representation, and representation from high performing OPOs and OPOs with the current highest number of DCD donors. We are currently working to add hospital administration representation.

The charge of the work group is to develop an outline of the important elements that must be addressed in a DCD recovery protocol. It is the intent of the work group to identify and list the overview of elements that must be addressed in OPTN member DCD protocols; it is not the intent to be prescriptive in how members meet the recommendations.

The work group held its initial meetings via teleconference on August 17 and 18, 2006. The work group discussed its charge and also agreed that its role should extend to offering resources and references to OPOs and transplant hospitals that may be working to determine how to address the model protocol elements in their specific DSA. The group noted that the final outline document from the work group should be intended to both assist OPOs and transplant hospitals in taking steps to put policies and protocols in place, and also to reinforce the importance of utilizing and complying with the protocols once implemented. The work group also noted the importance of keeping the outline of protocol elements “high level”, i.e., to identify general areas and elements to be addressed, but to also allow for the individual circumstances of individual DSAs and organizations. The group further noted the importance of maintaining a tone or statement of strong support for the practice of DCD. The group suggested drafting a mission statement to be included as an introduction to the final document outlining DCD recovery protocol elements to be addressed.

Margaret R. Allee RN, MS, JD, Chair of the Ethics Committee, noted that the Ethics Committee is submitting a document containing ethical guidelines for DCD recover to the Board for its approval at the September 2006 meeting. The group noted that this document may be an important addition to the resources and references to accompany the final protocol element document. The group further noted that having UNOS as the sponsoring organization of the document may be helpful; some members of the group agreed that transplant hospitals may perceive UNOS as a neutral third party, and this perception may allow DCD resources and recommendations to be better received.

The work group noted that a great deal of work has already been done in the donation and transplant community around DCD recovery and protocol development. The work group agreed that its charge may be most effectively met by organizing and clarifying existing resources and recommendations. The work group identified the following four categories to set the structure of the final document outlining DCD recovery protocol elements to be addressed:

- Ethics
- Clinical Protocols and Practice
- Conflict of Interest
- Financial Aspects

Work group members volunteered to work in small groups to address the components of each of the last three categories; following the development of model elements for these categories, representatives from the Ethics Committee reviewed the elements and offered comments and feedback.

At the December 2006 Board meeting, the joint OPO-MPSC work group, under the auspices of the Committee, asked that the Board to approve the following proposal: ****RESOLVED**, that the following model elements be adopted as new Attachment III to Appendix B of the OPTN Bylaws and serve as required standards for OPO and transplant hospital DCD recovery protocols, effective March 30, 2007:

ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS

Introduction: The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish required standards for OPOs and transplant hospitals to meet in developing, reviewing and improving DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices.

Donation after Cardiac Death Recovery Protocol Model Elements

A. Candidate selection

1. Non-recoverable neurological injury and/or other system failure resulting in ventilator dependency
2. Decision to withdraw life sustaining measures made by care giving team and legal next of kin.
3. Assessment of whether death is likely to occur within a time frame that allows donation; how this assessment is conducted and who performs it is to be collaboratively determined by the local OPO and transplant hospital.

B. Consent

1. Discussion with legal next of kin following decision to withdraw life sustaining measures.
2. Legal next of kin to be informed of and consent to any procedures or drug administration performed for the purposes of organ donation (i.e. heparin, regitine, femoral line placement, lymph node incision, bronchoscopy.)
3. Clearance from medical examiner/coroner.
4. Determination of location of withdrawal of life-sustaining measures and option for family presence.
5. Plan for patient care if death does not occur in set timeframe.

C. Patient Management

1. Support/care of patient managed by hospital; OPO available to collaborate to offer recommendations

2. If applicable, placement of femoral cannulas and administration of pharmacologic agents (regitine, heparin) for the sole purpose of donor organ function.

D. Withdrawal of Life Sustaining Measures

1. Address Do Not Resuscitate (DNR) orders.
2. Determination of location and process for withdrawal of life sustaining measures (i.e. ETT removal, termination of blood pressure support medications)
3. Determination of who administers and facilitates palliative care; measures in place to ensure that no member of the palliative care team has a conflict of interest in the donation process.
4. Determination of appropriate prepping and draping for recovery.
5. Family location during withdrawal of life sustaining measures.
6. Determination of how long recovery team will wait (typically between 1-2 hours)
7. Plan if patient does not expire within time frames allowable for donation.

E. Pronouncement of Death

1. Determination of which member of the care team will pronounce death.
2. Method of declaring cardiac death.
3. Statement of waiting period—from the declaration of death to the incision, not less than two minutes.
4. Declaration and documentation of death by member not involved with organ recovery or transplant team

F. Organ Recovery

1. Physical separation of transplant center recovery team and the donor from the time of withdrawal of life sustaining measures through the declaration of death.
2. No member of the transplant recovery team shall participate in the declaration of death or in the administration of comfort care measures or in providing guidance or recommendations in dosing of comfort care.

G. Financial Considerations

1. OPO policy to address point at which the OPO will assume financial responsibility of donation process
2. OPO policy to ensure no donation related charges are passed to donor family

Following discussion at the December 2006 Board meeting, the above resolution was amended to reflect a more encompassing and non-prescriptive outline of DCD recovery protocol model elements to be addressed in all OPO and transplant hospital DCD recovery protocols. The Board approved the following resolution: ****RESOLVED**, that the following model elements be adopted as new Attachment III to Appendix B of the OPTN Bylaws and should be incorporated into OPO and transplant hospital DCD recovery protocols, effective March 30, 2007:

ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS

Introduction: The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices.

Donation after Cardiac Death Recovery Protocol Model Elements

- A. Candidate selection
 - B. Consent
 - C. Patient Management
 - D. Withdrawal of Life Sustaining Measures
 - E. Pronouncement of Death
 - F. Organ Recovery
 - G. Financial Considerations
2. Imminent Neurological and Eligible Death Data Collection Project. The current OPTN contract requires that, "...patient-level data shall be collected from all OPOs and maintained on all eligible deaths and imminent deaths..." This requirement calls for (1) a definition of imminent death to be developed and approved, and (2) that a data collection system be developed to allow for the collection of patient-level data from all OPOs.

Last year, the OPO Committee completed a pilot project collecting patient level data on all eligible deaths from 11 participating OPOs (one from each region, of varying sizes, data capabilities, and eligible potential.) The objectives of the pilot project were to analyze possible predictive factors for conversion and to evaluate the feasibility of completing added data collection. The SRTR noted that the data from the pilot study suggested that age, race/ethnicity, and cause of death were significant predictors of conversion. In follow-up calls held by UNOS staff with the 11 participating OPOs, the OPOs noted that the data collection (for eligible, patient level data) was possible and feasible with current OPO resources.

Jeff Orłowski serves as the Chair of the group working on the current imminent and eligible death data collection project. At the April 2006 meeting, Mr. Orłowski reported to the full

Committee that the intent of the project is to help increase knowledge about donor potential, identify the prevalence of cases in which clinical brain death parameters are met but brain death is not declared, to improve the standardization and validity of reported donor data, and possibly to help to develop future reporting definitions for DCD potential and DCD eligible. The work group for this project met via teleconference on February 15, 2006 and March 27, 2006, to discuss possible paths forward and resources for developing a reporting definition for imminent death and a data collection system for patient level data for all eligible and imminent deaths.

After discussion and review of the materials, the consensus of the Committee was to use the AOPO death record review definition as the foundation for the development of an OPTN imminent death definition. The Committee noted that the imminent death definition should reflect the “next ring out” of donor potential from eligible deaths, e.g. - potential donors referred by hospitals to OPOs based on identified clinical triggers (GCS, absence of 3 or more brain stem reflexes, laboratory evidence, etc.) The AOPO death record definition is well established and well known within the OPO community; some OPOs currently use this definition as the basis for their own internal database tracking of donor potential and missed donor potential identified in death record reviews. At the April 2006 meeting, Virginia McBride, HRSA noted that while the OPTN reporting definition for eligible deaths serves as a metric of OPO and DSA performance evaluation, the future OPTN reporting definition for imminent deaths would be used solely for the purpose of identifying potential areas for improvement.

In preparation for presentation to the Data and Information Committee, AOPO Procurement Directors Council and Medical Directors Meetings at the June 20-23, 2006, AOPO annual conference, the work group met via teleconference on June 7, 2006, to finalize a draft of the imminent death definition and an overview of the project. The Committee noted that feedback and support from the OPO community in the development of a new standardized reporting definition is critical to the success of the project.

Representing the Committee, Jeff Orłowski, Charles Alexander, and Deborah Savaria presented the draft definition and overview of the project at the Medical Directors, Procurement Directors, and Data and Information Committee meetings, respectively. The work group reconvened on August 22, 2006 to discuss the feedback from the AOPO meetings.

The proposed reporting definition of imminent death and the OPTN reporting definition of eligible death would be mutually exclusive; an imminent death by proposed definition would not be reportable as an eligible death and an eligible death by definition would not be reportable as an imminent death. For consistency of data reporting, the exclusion criteria noted in the proposed imminent definition would be the same as the exclusions to the OPTN reporting definition of eligible death. Reporting for imminent deaths would also follow the same guidelines, as applicable, of reporting an imminent death “independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice.” This consistency with the OPTN eligible death definition is significant in that it continues the consistency in data reporting begun with CMS adopting the OPTN eligible death definition as its definition for eligible death. Numbers regarding eligible deaths serve as the denominator of two of the CMS OPO performance measures.

In addition, in order to evaluate the data burden and estimate the possible missed potential that could be identified through the reporting of imminent deaths, the Committee work group agreed to develop and implement a data collection PDSA. This initial PDSA is intended to give a general idea of the range of reportable imminent deaths per DSA using the draft proposed definition; this informal survey is intended to help guide the second phase of the project.

- *Plan:* Each member of the OPO Committee work group affiliated with an OPO (9 OPOs are represented on the work group) will submit a completed data survey by July 15, 2006.
- *Do:* For the months of January and February of 2006, complete the survey with the following data (by month)
 - Total number of recovered organ donors who are CMS eligible (no DCD or over 70 donors)
 - Total number of CMS eligible deaths including those referred and those identified on Death Record Review (DRR)
 - Total number of deaths meeting the proposed definition of Imminent Death, including those referred and those identified on DRR
- *Study:* Review data for general estimate and current feasibility of additional data collection using the proposed imminent death definition.
- *Act:* Evaluate results and plan next step

Data received to date suggest that the potential estimate of donor potential identified through imminent death reporting appears to be approximately 15-20 %; this percentage would be substantial if it applies nationally.

At its August 16, 2006, meeting, the POC reviewed the original draft of the imminent death definition and an overview presented by Jeff Orlewski, and noted its support that the definition is based on common guidelines approved by the American Neurological Association (ANA.) The POC also noted that the imminent death definition appears to be a natural evolution from the updated eligible death definition.

At its September 2006 meeting, the Board of Directors approved the following definition proposed by the Committee: ****RESOLVED**, that the following imminent death definition be approved for adoption as the UNetsm definition for reporting of imminent deaths, effective pending distribution of appropriate notice and programming on UNetsm.

Imminent Neurological Death Definition: Patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes or a GCS < 5 but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy, and who eventually progresses to cardiac death (during the referred hospitalization.) Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

To continue its work in developing the data collection system to collect patient level data on all imminent and eligible deaths, the work group met via teleconference in September and October of 2006, and discussed the project with the full committee at its October 17, 2006 meeting. The project is in the final stages of system design and is slated for late March 2007 implementation; the work group continues to identify what data elements to include in data collection for imminent neurological death, eligible death-no consent, donor, and consent not recovered cases. The system is currently designed to act in effect as an electronic decision tree allowing OPOs to import data from their databases to UNetsm. The electronic decision tree design is intended to both reduce data entry burden on OPOs and to create standardization of data reporting and thus increased validity of data used in analysis. The system will also allow for manual entry for smaller OPOs that may not have the electronic database capabilities at the time of implementation.

In order to meet the contract requirement for patient level data collection on all imminent and eligible deaths, modifications are required to Policy 7.0 (Data Submission Requirements.) The Board approved the following proposed modifications to Policy 7.0: ****RESOLVED**, that the following modifications to Policy 7.0 (Data Submission Requirements) shall be approved and implemented pending notice and programming:

7.0 DATA SUBMISSION REQUIREMENTS

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNetSM, beginning January 1, 2003. All OPOs are responsible for submission of patient level data for all consented donors, consent not recovered potential donors, imminent neurological and eligible deaths in its DSA. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms. ~~Each OPO also is responsible for submission of hospital-specific death notification, donor eligibility and consent information.~~ Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory. Recipient transplant centers are responsible for submission of Recipient Feedback information, Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, transplanted or followed at the center.

[No proposed changes 7.1 to 7.6]

7.7 SUBMISSION OF DEATH NOTIFICATION INFORMATION

All ~~monthly imminent neurological, non-consented eligible death notification information~~ and consent not recovered death notification information must be submitted by the OPO ~~for each donor hospital before the close of the subsequent calendar month~~ within 30 days of the date of the death notification.

[No further proposed modifications to Policy 7.0]

4. Addition of Leprosy to the List of Exclusions to the OPTN Eligible Death Definition. After continuing review of the list of exclusions to the OPTN eligible death definition, UNOS Medical Director Myron Kauffman, MD recommended to the Committee that Leprosy be added to the list exclusions to the definition. Dr. Kauffman also serves on the Operations Committee Disease Transmission Advisory Group; this group is charged with reviewing cases of donor related disease transmission and offering recommendations to policy and education regarding practice based on case review.

The Committee fully supported Dr. Kauffman's recommendation and voted unanimously to bring the following proposal to the Board of Directors for approval: ****RESOLVED**, that Leprosy shall be added to the list of exclusions to the OPTN eligible death definition.

Although it is recognized that this definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

Active infections (specific diagnoses):

Bacterial:

Tuberculosis

Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis

Leprosy

See "sepsis" below under "General"

Viral:

HIV infection by serologic or molecular detection

Rabies

Reactive Hepatitis B Surface Antigen

Retroviral infections including HTLV I/II

Viral Encephalitis or Meningitis

Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia

Acute Epstein Barr Virus (mononucleosis)

West Nile Virus infection

SARS

Fungal:

Active infection with Cryptococcus, Aspergillus,
Histoplasma, Coccidioides
Active candidemia or invasive yeast infection

Parasites:

Active infection with Trypanosoma cruzi (Chagas'),
Leishmania, Strongyloides, or Malaria (Plasmodium sp.)

Prion:

Creutzfeldt-Jacob Disease

General:

Aplastic Anemia
Agranulocytosis

Extreme Immaturity (<500 grams or gestational age of <32 weeks)

Current malignant neoplasms except non-melanoma skin cancers such as basal
cell and squamous cell cancer and primary CNS tumors without evident metastatic
disease

Previous malignant neoplasms with current evident metastatic disease

A history of melanoma

Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple
Myeloma

Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis
defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without
response to treatment or resuscitation

Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis

The Committee requested that this proposal be withdrawn from consideration by the Board of Directors at the December 13-14, 2006, Board meeting. The Committee noted that adding Leprosy to the list of exclusions to the eligible death definition would result in a difference between the OPTN and CMS eligible death definitions. Following the Board's March 2006 approval of the new OPTN eligible death definition, CMS adopted the new OPTN eligible death definition. CMS adopting the OPTN eligible death reporting definition was significant in its creation of uniform standardized performance measures for and data comparison across OPOs.

CMS follows a required process for definition revision and cannot currently update its definitions with the same ease as the OPTN. The Committee would thus like to pull the current proposal to alter the current OPTN eligible death reporting definition in favor of working towards continued uniformity in performance standard measure between the OPTN and CMS.

II. Other Issues

5. OPTN/UNOS Policy Proposals for Public Comment, August 28-October 27, 2006. The Committee reviewed and offered comment on the following policy proposals [Please see Item 1, Page 1 for discussion of the proposed Bylaw Amendment Regarding Donation after Cardiac Death (DCD) Protocols for all Organ Procurement Organizations (OPOs) and Transplant Hospitals, OPO Committee]:

2. **Proposed Allocation System for Broader Sharing for Livers in Region 8 (Liver and Intestinal Organ Transplantation Committee).** This proposed alternative allocation system is intended to create a system for broader sharing for livers in Region 8. This system was created as a result of a Board of Directors resolution that instructed Region 8 to develop such a plan.

The OPO Committee reviewed the proposal at its October 2006 meeting and noted that it unanimously supports the intent of broader sharing of livers; however, the Committee questioned why this proposed sharing agreement would be permitted if no other alternative allocation systems are currently allowed.

The Committee noted its concern regarding a potential lack of consistency and equity in policy and allocation. The Committee was informed at its October 2006 meeting that the Policy Oversight Committee (POC) discussed a recommendation that this proposed allocation system be proposed in the form of a prospective study with a data collection method outlined as part of the proposal.

4. **Proposed New OPTN/UNOS Policy 3.11.4.2 (Combined Liver-Intestine Organ from Donors 0-10 Years of Age) (Liver and Intestinal Organ Transplantation Committee).** This proposal will allow combined liver-intestine grafts to be allocated to national candidates from the liver waiting list if there is no local Status 1A or 1B candidates or candidates with a PELD score of 20 or greater. The intent of this proposal is to increase the availability of smaller size organs for pediatric liver-intestine candidates.

The OPO Committee reviewed the proposal at its October 2006 meeting and unanimously supported the intent of the proposal: trying to reduce deaths on the waitlist.

The Committee discussed that the outcome of the policy may be contrary to the intent in that multivisceral candidates may be disadvantaged by this policy. The Committee also noted that it is difficult to consider the proposal and its potential impact given that this patient population offers too small a sample to yield significant data analysis.

6. **Proposed Modifications to OPTN/UNOS Policy 3.6.11 (Allocation of Livers for Segmental Transplantation) (Liver and Intestinal Organ Transplantation Committee)** This proposal will utilize specific criteria to identify potential split liver donors on every OPO match run while also identifying candidates who have indicated they would be willing to accept a segmental graft. The intent of this proposal is to initiate discussions between the OPOs and the transplant centers and possibly increase the utilization of split liver transplants.

The OPO Committee discussed this proposal at its October 2006 meeting; the proposal was unanimously supported by the Committee.

The Committee further discussed its support for working to address how to develop a method to define a "splittable" donor liver. The Committee also noted its continued support for increased consideration of splitting donor livers for pediatric cases.

- 13. Proposed Modifications to OPTN/UNOS Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) (Thoracic Organ Transplantation Committee).** The purpose of this proposal is to modify the zones for thoracic organ allocation to accommodate the needs of Hawaii and potentially serve other organ procurement organizations as well. Zone D will be modified to be greater than 1500 miles up to and including 2500 miles from the donor hospital. The OPTN/UNOS Board approved the proposal in June 2006 to be implemented concurrent with public comment.

The OPO Committee reviewed this proposal at its October 2006 meeting and voted unanimously in favor of the proposed modifications.

- 16. Proposed Modifications to OPTN/UNOS Policy 3.5.11.3 (Panel Reactive Antibody Replacement of Panel Reactive Antibody with CPRA, the calculated frequency of incompatible donors having one or more unacceptable antigens (Histocompatibility Committee).** This modification primarily will apply to renal allocation but will also be applicable to all organ allocation for which the sensitization of the transplant candidate is considered. The intent of the proposed modifications is: to provide a more consistent basis for the identification of highly sensitized patients, to assign a calculated frequency of incompatible donors based on unacceptable antigens defined by the presence of HLA specific antibodies and by other criteria as defined by center specific protocols, to increase the consistency in the detection and identification of HLA specific antibodies by requiring use of more accurate and sensitive methods that are available to OPTN laboratories, and to improve the efficiency of organ allocation by reducing the number of predictably positive crossmatches.

The OPO Committee reviewed this proposal at its October 2006 meeting and voted to unanimously support the proposed modifications.

- 17. Proposed Modifications of Policy 2.2 (Evaluation of Potential Donors) (Membership and Professional Standards Committee).** The proposed modification clarifies the responsibilities of the Host OPO in undertaking specified evaluations of potential donors. In addition, it establishes the requirement that when specified evaluations are undertaken and the information is not available that the Host OPO must explain those circumstances.

At the request of the Membership and Professional Standards Committee (MPSC), the OPO Committee reviewed the initial draft of this proposal at its April 2006 meeting. The OPO Committee recommendations were reviewed and accepted by the MPSC, and are included in the current proposed modifications. The OPO Committee voted to unanimously support the current proposed modifications to Policy 2.2.

- 18. Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)** The proposal would require that the Host OPO provide biopsy results for both kidneys of all ECD and DCD donors and at the request of the surgeon and/or OPO for non ECD or DCD kidneys. The wedge technique for renal biopsy is to be utilized obtaining a tissue sample measuring at least 10mm x 5mm x 5mm. This sample size is calculated to capture approximately 100

glomeruli. Capture of less than 25 glomeruli will be considered an inadequate biopsy, and documentation on the donor form to explain rationale for inadequacy of tissue sample will be required. Separate standard report forms for frozen and permanent sections will be required for the tissue samples. This modification is intended to standardize renal transplant biopsy procedures and reporting methodologies to allow meaningful analysis in the determination of kidney allograft outcome data.

The OPO Committee reviewed this proposal at its October 2006 meeting and voted unanimously to oppose the proposed modifications. The Committee's concerns included the current debate regarding whether a biopsy is indicative of graft function, the variability regarding biopsy practice and experience, the incidence of hospitals where biopsies may not be available, the inclusion of DCD as a mandated biopsy category, and the responsibility for compliance with the proposed policy modifications focused solely on OPOs. The Committee noted that responsibility for policy adherence and standardization of biopsy practice should be shared by both the OPO and the recovering surgeon and transplant center. The Committee further noted that the proposed modifications seemed overly prescriptive in clinical practice; the Committee noted its support for OPOs having a biopsy policy and for a recommendation for standard biopsy practice.

Following the October 2006 OPO Committee meeting, the OAC Chair and Vice Chair noted that revisions had been made to the proposed modifications based on regional and committee feedback. The revisions include:

- New language stating that the intent of the policy is for shared responsibility between the OPO and transplant hospital/surgeon.
- Changing the proposed modification from a mandated practice to a suggested best practice.

The intent of the OAC in drafting this proposal is to work to reduce discard rates; biopsy findings are currently listed as the highest frequency of reason for discard. The OAC is trying to create standardized practice so that data evaluation of biopsy findings will be valid and effective in informing practice.

The OPO Committee supports the proposal with the current updated revisions to the proposed modifications to Policy 3.5.9.

6. OPTN/UNOS Policy Proposals for Public Comment, November 20, 2006 – January 19, 2007. The Committee reviewed and offered comment on the following policy proposals

1. Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)

The intent of this proposal is to decrease the number of discards of procured deceased donor kidneys and standardize the methodology for the reporting of renal biopsies. The proposal suggests that the host OPO, with cooperation of the procuring surgeon, provide biopsy results for both kidneys of all ECD kidneys and at the request of the surgeon for non ECD kidneys. The goal of improving the validity and accuracy of kidney biopsies is a good one and supported by members. Committee members commented that this proposed change may be problematic because the word "must" associated with minimum number of glomeruli required implies that there would be some form of penalty if the specimen fell short of the requirement.

This proposed change holds the OPO accountable for the results and actions of the transplant surgeon in obtaining the biopsy. A biopsy that is less than 25 glomeruli would require the OPO to document in the donor record the reason for the inadequate size. There was some confusion and questions were posed regarding what will happen to this information once collected. Some members agreed that it is an extra burden for the OPO to document this information accurately. For example: A visiting team recovers the liver and kidneys from a donor and the kidney biopsies are read after the visiting team has left the area with only 24 glomeruli visualized on biopsy. It will be the responsibility of the host OPO to locate the visiting recovery team to determine why the sample contained 24, rather than 25, glomeruli.

There are various reasons why a tissue sample would include less than 25 glomeruli, such as: poor surgical technique or the recovery team blaming the pathologist for not reading the biopsy properly. Members are unclear as to what is to be gained obtaining this information.

The policy also suggests that the biopsies be read at the donor hospital. Many OPOs with large service areas coordinate donors in hospitals where the pathologist may not be experienced in reading kidney biopsies. Perhaps the finding of 24 glomeruli is a result of an inexperienced pathologist reading biopsies, as opposed to pathologists from kidney transplant centers who read such biopsies frequently. One member commented that to secure a biopsy for non-ECD kidneys "upon request" is too vague and could add unnecessary cost to the system if not administered correctly.

Finally, the list of information required on biopsies will not be provided on a regular basis, even by experienced pathologists. OPOs have challenges obtaining information such as number of glomeruli and percent sclerosed with a mention of vasculature. To secure the list presented in the policy proposal would be difficult at best. The OPO will need to provide reasons for "non-reporting" of the data elements when OPO staff is dependent on the pathologist reading the biopsy.

Although members supported the standardization of the biopsy protocol, concerns were voiced regarding the need for all ECDs to be biopsied. Some agreed that this should best be managed by the accepting surgeon, who may also be the recovering surgeon in some cases, and that the receiving center can perform biopsies at any time.

Committee members voiced concerns that, although this proposed policy is a good start to standardizing the need for biopsies, it continues to tie the OPO to the evaluation of compliance with this practice. It should not be the OPO personnel who are responsible for the procuring surgeon's willingness to do a biopsy, get an adequately sized specimen, or document if and why an adequate specimen was not obtained. The host OPO has little, if no control over surgeons in this situation and should not be held accountable for their actions. The Committee also questioned whether the lack of documentation in the donor record makes the OPO or the procuring surgeon out of compliance. There have been discussions at regional meetings over this issue.

The Committee did not approve this proposed change with a vote of 3 in favor, 6 opposed, and 0 abstentions.

2. Proposed Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee).

The proposed policy modifications will provide procedures for packaging and transporting of donated organs that are not addressed by current policy.

The Committee supported this proposed change with a vote of 8 in favor, 0 opposed, and 1 abstention.

3. Proposed Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) (Operations Committee)

The objective of the proposed policy modification is to improve patient safety by requiring verification of the UNOS Donor ID number for all organs prior to transplant.

The Committee supported this proposed policy change with a vote of 9 in favor, 0 opposed, and 0 abstentions.

4. Proposed Modifications to Data Elements on UNetSM Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee)

The intent of the proposed policy change would be to significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant. Decreasing the amount of data needed and eliminating the need to track 5-year social data would be very helpful as frequently this information is difficult to find. One member commented that this reduction might encourage compliance with meeting data entry deadlines.

The Committee approved this proposed change with a vote of 8 in favor, 0 opposed, and 2 abstentions.

7. Data Review, National DSA Dashboard. In 2006 the Board of Directors established goals for each OPTN/UNOS committee to address over the current two year Board cycle. One of the goals outlined for the OPO Committee is the oversight and use of the National DSA Dashboard. The Dashboard was developed under the auspices of the DSA Task Force and the UNOS Breakthrough Collaborative team, The Revolution. The DSA Task Force is not a permanent standing committee and was established with a two year time frame ending in 2007. The Committee noted that the data and continued future distribution of the National DSA Dashboard is essential to ongoing evaluation of and improvement in practice and collaboration for all three estates, OPOs, donor hospitals, and transplant centers. The Committee agreed that it, as the DSA Task Force two year term ends, would assume the review and oversight of the National DSA Dashboard. The Committee also agreed that review of the DSA Dashboard may serve to replace and expand the current data review prepared for each meeting; the DSA Dashboard incorporates the data currently reviewed by the Committee and adds layered specificity (nation, region, DSA) and the ability to sort and isolate data by topic, institution, etc. The Committee agreed to form a work group to address how to best incorporate the National DSA Dashboard into the ongoing work of the Committee, how to best use the Dashboard as an effective tool to set fair performance standards and monitor trends, and to establish evidence based measures for identifying both excellent and below average goal performance.

8. Acceptance Listing and Acceptance Practice Report. In 2006 both the MPSC and the DSA Task Force initiated efforts to help educate transplant centers regarding their current listed acceptance criteria and their current acceptance practices. The intent of the report was to support the ongoing work of improving the efficacy of organ offers and the accuracy of listed acceptance criteria. The first pilot report was prepared for and distributed to all kidney transplant centers in the summer of 2006. The report outlined the current listed acceptance criteria, recent organ offers, and the outcome of the organ offers (acceptance, decline).

As its last project and charge, the DSA Task Force will be focusing the remainder of its time on the development of a tiered acceptance system, a complement to DonorNet 2007 electronic organ offer placement. It was suggested by HRSA representatives that the acceptance listing and acceptance practice report be continued and expanded under the auspices of the OPO Committee. The Committee discussed and agreed with the importance of this project and noted that the report may be best received from the Operations Committee. The Committee noted that acceptance listing and practice is a broad systems issue; the Operations Committee is charged with the oversight and improvement of operational process and system efficiency. Further, the Committee noted that the report may be better received as peer education if the sponsoring committee is composed of transplant physicians and surgeons; the Operations Committee consists of a balanced representation of transplant physicians and surgeons, as well as OPO executives.

At the October 2006 meeting, Marlon Levy, MD, Chair of the Operations Committee and current Member At Large of the OPO Committee, noted the importance of this report in relation to ongoing efforts to streamline organ placement and improve the efficacy of the organ offer process. Dr. Levy volunteered to continue the acceptance listing and acceptance practice report under the auspices of the Operations Committee. In order for this issue to be considered as a new business item for the next Operations Committee meeting, Dr. Levy asked that a memo be sent to the Operations Committee from the OPO Committee Chair noting the discussion from the October 2006 OPO Committee meeting and the importance of the continuation and expansion of the acceptance listing and practice report.

9. OPTN/UNOS Report of Disease/Malignancy Transmissions, January 1-October 9, 2006. Myron Kauffman, MD, OPTN Medical Director, joined the October 2006 Committee meeting via teleconference to discuss the current year to date reported donor related disease/malignancy transmissions. The Committee reviewed a summary of 49 cases reported between January 13, 2006, and September 26, 2006; 10 of the 49 cases reported were either not donor related cases or were false positives. Dr. Kauffman noted that the Disease Transmission Advisory Group (Operations Committee) currently oversees the reporting process, reviews reported cases, and works collaboratively with other government agencies to ensure communication and patient safety. The Committee noted the importance of this information and the need to disseminate this information to the donation and transplantation community on a regular basis to educate, inform, and safeguard patient safety. The Committee requests that the Operations Committee Disease Transmission Advisory Group develop and effective means of communicating this information and teaching best practices regarding patient safety and donor related disease/malignancy transmissions. Dr. Levy, Operations Committee Chair, noted that the Operations Committee is currently developing an e-newsletter that may serve as a good vehicle for dissemination of patient safety information and best practices. In addition, Robert Metzger, MD, a guest of the Committee, recommended that the Disease Transmission Advisory Group develop a recommended protocol for the evaluation and reporting of Chagas Disease.

The Committee also reviewed slides presented by Dr. Kauffman on disease and malignancy transmission reported to the OPTN from January 1, 2006 through July 31, 2006. During this time period, there were eight donor related renal cell carcinoma transmissions and seven potential donor transmitted tumors. Dr. Kauffman noted that his research suggests that small renal cell carcinomas are frequent and transmission potential is relatively low. He further noted that his research suggests that the renal cell carcinoma (RCC) may be excised and the kidney transplanted safely. Dr. Kauffman stressed the importance of careful examination of deceased donor kidneys. Per his research and review of the data, Dr. Kauffman noted that a history of melanoma is a strong contraindication to donor organ recovery. He further noted that a non-traumatic, non-hypertensive intracranial hemorrhage (ICH) may be considered a tumor metastasis until proven otherwise. The Committee discussed this suggestion and other possibilities for a non-traumatic, non-hypertensive ICH (e.g.-aneurysm) and agreed strongly that extensive exploration of donor organs before recovery is essential to ensure recipient safety. In response to the data presented by Dr. Kauffman on renal cell carcinomas, the Committee agreed to ask the Operations Committee Disease Transmission Advisory Group to offer a recommended protocol to evaluate and clean kidneys during recovery/ prior to the transplant of other donor organs. The Committee feels strongly that it is important for the Operations Committee and the community to act on the current donor related disease/malignancy transmission information to improve and protect patient safety.

- 10 OPTN/UNOS Membership and Professional Standards Committee (MPSC), Response to OPO Committee Regarding Review of Policy 3.3.6. The Committee reviewed a September 20, 2006, memo from the MPSC regarding proposed modifications to policy 3.3.6 (Center Acceptance of Organ Offers.) The MPSC responded in the memo to the OPO Committee's request to provide further details regarding three situations considered by the MPSC in which an allocation policy was altered after unconditional acceptance and without mutual agreement of the Host OPO and originally intended recipient transplant center.

Policy 3.3.6:

If an organ is offered and accepted without conditions, the Host OPO and recipient transplant center shall be bound by this transaction unless there is mutual agreement on an alternative allocation of the organ.

In a memo dated May 8, 2006, the OPO Committee noted that there are a number of situations in which it may be appropriate to alter the allocation priority or offer. For example, if a mistake is made inadvertently in the initial offer priority, the OPO would want to correct the mistake and appropriately follow allocation policy. The Committee further noted that offers always have inherent conditions of time dependent on donor stability, changing family needs, hospital staff and operating room availability. Moreover, Policy 3.4.2 (Multiple Organ Retrieval) outlines a condition under which an OPO may alter an allocation priority after acceptance and without mutual agreement of the OPO and transplant center.

Policy 3.4.2:

After a Member indicates its initial acceptance of an organ, the transplant centers or OPOs involved must agree upon the time that multiple organ procurement will begin. If the procurement time cannot be agreed upon, the Host OPO may withdraw the offer from the transplant center or OPO unable to agree upon a time for procurement to begin.

The Committee requested further information regarding the situations considered by the MPSC so that an informed recommendation could be made to the MPSC. The MPSC responded in its September 20, 2006, memo with an outline of three situations previously

reviewed by the MPSC regarding Policy 3.3.6. The three situations ranged from the rescinding of a kidney payback offer as a result of three organ offers being made with only two organs available, the retraction of liver payback offer due to miscommunication of payback status, and two primary offers made on one available kidney due to the delayed relay of information.

The Committee reviewed and discussed each of the three situations outlined in the MPSC memo. After discussion, the Committee agreed that the Policy 3.3.6 is clearly stated and that no revisions are needed to clarify the intent or interpretation of the policy. The Committee noted that some situations are due simply to miscommunication and/or lack of information in navigating a complicated and time sensitive placement and allocation process. The Committee noted its appreciation to the MPSC for its time in outlining these situations and concerns, and for the MPSC's continued diligence in reviewing complaints submitted regarding potential process failures.

11. Gamma Glutamyltransferase (GGT) Documentation, Request to Review Current OPTN/UNOS Requirement. At its October 2006 meeting, the Committee reviewed a request submitted by Phyllis Weber, Chief Executive Officer of the California Transplant Donor Network (CTDN). Ms. Weber requested that the Committee review Policy 2.2.7.3, (Minimum Procurement Standards for an Organ Procurement Organization, Evaluation of Potential Donors) for potential liver donors. Ms. Weber noted in her request that CTDN was recently asked by UNOS to provide a corrective action plan to account for a lack of documentation on GGTs for many of their donors. Ms. Weber noted that this test is not available in many hospitals in the CTDN Donor Service Area (DSA) and is not currently a significant piece of information for CTDN DSA liver programs. Ms. Weber requested that the OPO Committee review the current policy regarding GGT to ensure that the policy reflects current practice standards.

The Committee reviewed and discussed the request and Policy 2.2.7.3 and agreed that GGT should not be included as required documentation for all potential liver donors due to current practice standards and test availability. Committee members from many regions noted that GGT is rarely requested by transplant centers and is not always available when requested. The Committee agreed to submit a request and recommendation to the Liver and Intestinal Organ Transplantation Committee to revise Policy 2.2.7.3 to list GGT as required if available and requested by the transplant center.

The Committee recommends the following revision to Policy 2.2.7.3:

- 1.2.7.3 For potential liver donors:**
- AST
 - ALT
 - Alkaline phosphatase
 - GGT (if requested and when available)
 - Total bilirubin
 - Direct bilirubin (if requested);
 - INR (PT if INR not available);
 - PTT; and
 - Blood group subtyping of ABO=A donors

**OPTN/UNOS OPO Committee
October 17, 2006 Meeting
New Orleans, LA**

Committee Members Attending

Charles Alexander, RN, MSN	Chair
Jeffrey P. Orłowski, MS, CPTC	Vice Chair and Region 9
Posy Durning, PA, CPTC	Region 1
Charles E. Wright, MD	Region 3
Samuel M. Holtzman	Region 4
PJ Geraghty, BS, CPTC	Region 5
Diana L. Clark	Region 6
Beth Plahn, RN, BA, MHA	Region 7
Martin D. Jendrisak, MD	Region 8
David D. Lewis, RN, BSN	Region 10
Lloyd H. Jordan, Jr., CPA	Region 11
Maureen Popke, RN, CCRN	At Large
Ladora A. Dils, RN, CPTC	At Large
Joseph Ferreira	At Large
Marlon Levy, MD	At Large
Dina Steinberger, PA-C	At Large
Deborah Savaria, RN, CPTC	Ex-Officio
Virginia McBride, HRSA	Ex-Officio

Committee Members Unable to Attend

Lori E. Brigham, MBA	Region 2
Daniel H. Hayes, MD	At Large
Jade K. Perdue, MPA	Ex-Officio

UNOS Staff Attending

Hilary Kleine-Czarda, MSW	Committee Liaison
John Rosendale, MS	Committee Biostatistician
Courtney Bland, MCIS	Committee Support Staff, Business Analyst (IT)
Lin McGaw, RN, MEd	Director, Professional Services Department
Kristal Wood	Committee Support Staff, IT

SRTR Staff Attending

Bob Wolfe, PhD
Eric Roys
Frankie LaPorte

Joint OPO-MPSC DCD Protocol Development Work Group, Roster

Charles Alexander, RN, MSN,	Chair
Anthony D'Alessandro, MD	
Juan Arenas, MD	
Posy Durning, PA, CPTC	
Tom Gonwa, MD	
Rick Hasz, MFS	
Rob Linderer, RN, BSN	
Virginia McBride, HRSA	Ex-officio
Tom Nakagawa, MD	
Jeff Punch, MD	
Alan Reed, MD	
Meg Rogers	
Randolph Steadman, MD	
Dina Steinberger, PA-C	
Michael Thibault, RN, BSN, CPTC	

UNOS Staff:

Sally Aungier
Hilary Kleine Czarda, MSW
Courtney Bland, MCIS
Lin McGaw, RN, MEd
John Rosendale, MS
David M. Kappus