OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE (TAC)
INTERIM REPORT

May 17, 2011
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The following is a summary of the TAC OPTN deliberations that occurred via Live Meeting on May 17, 2011. The TAC reviewed and discussed the following public comment proposals:

Proposal to Update and Clarify Language in the DCD Model Elements (Organ Procurement Organization and Organ Availability Committees)

Committee Response: The impact for the OPTN members is that each donor hospital and transplant center will have to change their policy to reflect the change. In most institutions, this is a cumbersome process that can take many months, consuming many resources in those months. Because it can/does take many months, many hospitals will be "out of compliance" as their policy will not be updated on the date this new change is effective, thus resulting in being cited by UNOS. In some hospitals, it takes at least six months from the time a policy revision is made to go through the entire approval process.

The Committee also had some suggestions regarding the proposal language and suggested that the policy include a definition of circulatory death that is consistent with other professional societies across the country.

Regarding the language at the bottom of page 8 and top of page 9 under, *"Protocols OPOs and transplant centers shall establish protocols that define the roles and responsibilities of the OPO and transplant centers for the evaluation and management of potential donors, organ recovery and organ placement in compliance with OPTN policy."*

A committee member pointed out a potential conflict with this language and the language in UNOS Policy 2.0 (Standards for OPOs). In Policy 2.0, the responsibility for the evaluation and management of organ donors rests solely **on the "Host OPO."** This wording would potentially conflict with the wording in Policy 2.0 by having one policy that makes it a shared responsibility (OPO and transplant center) and one that makes it the responsibility of the Host OPO.

The following suggested wording would more accurately capture the intent of what is attempting to be conveyed and avoids the unintended conflicts between the wordings of the two policies:

Suggested wording:

B. Protocols
OPOs **in consultation with their affiliated** transplant centers shall establish protocols that define the roles and responsibilities of the OPO and transplant centers for the evaluation and management of potential **DCD** donors, **DCD** organ recovery, and **DCD** organ placement, in compliance with OPTN policy.

On Page 9, section E, *"**Withdrawal of Life Sustaining Medical Treatment/Support ~~Measures/Patient Management~~** Before withdrawing life-sustaining medical treatment or ventilated support, the OPO is required to conduct a timeout to:"*

The wording as proposed is vague and could be left open for interpretation.

Suggested wording:

Before withdrawing life-sustaining medical treatment or ventilated support, the OPO **must communicate with the surgical recovery team including the surgeons and operating room personnel, and other health care professionals that will be present during the withdrawal of life sustaining treatment** ~~is required to conduct a timeout~~ to:

1. Verify the patient's identification, etc.

Feedback on the last sentence in Section E on page 10 which reads as follows:

"No member of the Organ Recovery team or OPO staff may guide or administer palliative care or declare death."

This sentence may be overly broad and restrictive in its construction. For example, the health care team members that may be withdrawing treatment and providing the actual comfort care can and frequently do have questions for the OPO staff before, during and after the DCD process. So while the OPO staff member will not actually administer comfort care medications, or withdraw the endotracheal tube, they may be asked guidance questions by the healthcare team members. The Committee is concerned that the wording as proposed would not allow the OPO staff to answer such questions for fear of "guiding" such activities.

Also, the definition of palliative is becoming increasingly broad, and it may include simple comfort measures such as putting an extremity in a more comfortable position for a patient, and is not the type of care we are concerned that an OPO staff member might be engaged in performing.

Suggested wording:

No member of the Organ Recovery team or OPO staff may ~~guide or~~ administer ~~palliative care~~ **comfort/palliative care** medications prior to **circulatory** death**, nor may they** declare **the patient's** death.

Also, on page 10, Section F, under pronouncement of Death there is the following statement:

"Pronouncement of death can only be made after a sufficient time period has passed, ***as defined by hospital policy****."*

The problem with this statement is that OPOs still perform DCD recovery in hospitals that do not have DCD Hospital Policies. Therefore, it is impossible for those hospitals to comply with policies they do not have. Also, it is not the OPTN's responsibility to assure that hospital's have such policies nor are they responsible for the hospital's compliance with their own policies. Since it is not the OPTN's responsibility to oversee all the hospitals in the country in this manner, the last proposed clause of "as defined by hospital policy" should be deleted. (11-Support with suggested changes, 0-Oppose, 0-Abstain)

Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B (Pediatric and Liver and Intestinal Organ Transplantation Committees)

Committee Response: The Committee discussed and unanimously supported this proposal as written. (11-Support, 0-Oppose, 0-Abstain)

Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B (Pediatric Transplantation Committee)

Committee Response: The Committee discussed and unanimously supported this proposal as written. (11-Support, 0-Oppose, 0-Abstain)

Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability (Thoracic Organ Transplantation Committee)

Committee Response: The Committee discussed and unanimously supported this proposal. However, the Committee would like the Thoracic Organ Transplantation Committee to take into consideration that there may be resistance from the abdominal surgeons due to the potential delay in abdominal organ procurement by the thoracic surgeons, additional costs, and transplant centers could receive resistance from OPOs for requesting CT scans for standard criteria organs. (11-Support, 0- Oppose, 0-Abstain)

Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to ModifyPolicy 3.7.6.3 for Currency and Readability (Thoracic Organ Transplantation Committee)

Committee Response: The Committee discussed and unanimously opposed this proposal. The Committee agreed that this policy adds a significant layer of complexity for lung programs. The number of policy changes and the new requirements in those changes are making it extremely difficult for centers to reach 100% compliance. This policy creates a significant workload for transplant centers making it difficult for centers to remain in compliance, takes away from actual patient care, impacts transplant centers' financial resources and increases UNOS audit time. The Committee questioned the data supporting the decision to change the policy to a 14 day requirement and would like to know if there is any supporting data regarding the percentage of patients that are receiving transplants with a LAS greater than 50 that would have had a LAS of less than 50 if retested at the suggested 14 days. (0-Support, 11-Oppose, 0-Abstain)

Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time (Thoracic Organ Transplantation Committee)

Committee Response: The Committee discussed and supported this proposal. The Committee suggested that the Thoracic Organ Transplantation Committee continue to discuss the inequities of this policy. They agreed that the total artificial heart population that is discharged from the hospital with a portable driver needs to be addressed and suggested further discussion regarding the new sub-segment of patients with mechanical circulatory support. The Committee also discussed the fact that this proposal proposes changing policy to accommodate a clinical trial. The Committee commented that the reason for this policy proposal is that hospitals are now able to discharge patients with total artificial hearts and under current policy the patient would lose his/her Status 1A time. In essence, the proposed policy change is being driven by the fact that patients with total artificial hearts can be discharged with a portable driver, which is currently in clinical trial. (10-Support, 0-Oppose, 1-Abstain)